**Transcript of**

**Meeting of the Pesticide Program Dialogue Committee**

**NRECA Conference Center**

**4301 Wilson Boulevard**

**Arlington, Virginia**

**October 29, 2003**

For The Record, Inc.
Waldorf, Maryland
(301)870-8025

**A T T E N D E E S**

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|---|---|
| **Dr. Lori Berger** | **CA Minor Crops Council** |
| **Robert Rosenberg** | **National Pest Management** |
| **Gerret Van Duyn** | **National Cotton Council** |
| **Carolyn Brickey** | **Institute for Environment and Agriculture** |
| **Dr. Richard Liroff** | **World Wildlife Fund** |
| **Dr.Jennifer Sass** | **Natural Resources Defense Council** |
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| **Erik Nicholson** | **United Farmworkers of America** |
| **Troy Seidle** | **People for Ethical Treatment of Animals** |
| **Dr. N. Beth Carroll** | **Syngenta** |
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| **Dr. Leonard Sauers** | **Procter & Gamble Company** |
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| **Jay Vroom** | **CropLife America** |
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| **Dr. Alan Lockwood** | **Physicians for Social Responsibility** |
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| **Phil Benedict** | **Vermont Dept of Agriculture** |
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| **Allen Jennings** | **Office of Pest Mgmt,USDA** |
| **Dr. Melody Kawamoto** | **National Institute for Occupational Safety And Health, CDC** |

**P R O C E E D I N G S**

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**MR. SHARP: Thanks to everybody for taking the time out again to come to this meeting. I know that many of you have invested a lot of time in these PPDC meetings over the years and it is always a very, valuable opportunity for all of us. For you all to come and present issues to us to have the dialogue to put the thinking into the issues and come with valuable feedback to us has always been a terrific help for us to guide our activities, and I look forward to another full day of that.**

**Today, I know we have a number of issues from non-animal testing, endangered species, updates on various issues, mosquito labeling and others. There's a laundry list of things that I know are important to all of you and important to us, and I look forward to all your comments on those.**

**There's, I know, several folks -- I think a few of you that are on PPDC and some that are not -- that are**

**going to be presenting at some of the sessions throughout the day today and tomorrow, and I want to thank those individuals for also taking time out to come and present on various issues and have a dialogue on various issues that are going to be brought up as well.**

**With that, I'm going to go ahead and stop and say -- also, it's good to have USDA up here with us and thank them for coming and participating in this. I think it's very valuable. This is a trend -- through PPDC and also through the CARAT Advisory Group and TRAC before that - of not only making sure that we're having a dialogue between stakeholders, but also making sure that we (EPA) and USDA are here to listen to all of these discussions and get the feedback from you on these issues**

**So, again thanks for USDA also for being here today and I'll turn it over to Burleson.**

**MR. SMITH: Thank you, Adam. Again, I would like to just echo the sentiments -- welcome to DC and thank you for your participation in this PPDC meeting. I find them always to be informative and seldom boring**

**because of the spirited discussions.**

**From the standpoint of the programs, we appreciate the opportunity to participate as a colleague to EPA in these meetings and look forward to discussions.**

**MR. JONES: Thanks, Adam and Burleson. Why don't we just go around the room right now and introduce ourselves.**

**MS. MONELL: Marty Monell, Deputy Director for Management in the Office of Pesticide.**

**MR. JENNINGS: Al Jennings, USDA.**

**MS. LINDSAY, Anne Lindsay, Deputy Director for Programs on Pesticides**

**MR. ELLENBERGER: Jay Ellenberger, Acting Director of the Field and External Affairs Division and Pesticides.**

**MS. SHACKLEFORD, Acting Director of the Special Review and Reregistration Division in the Pesticide Office.**

**MR. SEIDLE: Troy Seidle, Science Advisor of People for the Ethical Treatment of Animals.**

**DR. LIROFF: Richard Liroff, Worldwide Life Fund.**

**Dr. LOCKWOOD: Alan Lockwood, Professor of Neurology at the University of Buffalo and Chairman of the Environment And Health Committee of Physicians for Social Responsibility.**

**MS. BRICKEY: Carolyn Brickey, Protected Harvest.**

**MR. VROOM: Jay Vroom, CropLife America.**

**MR. SAUERS: Len Sauers, the Proctor and Gamble Company.**

**MR. BENEDICT: Phil Benedict, of the Vermont Agency -- (inaudible).**

**MR. JENNINGS: Allen Jennings, Office of Pest Management, USDA.**

**MS. LEWIS: Nancy Lewis, Department of Nutritional Science and Dietetics, University of Nebraska**

**DR. BERGER: Lori Berger, California Minor Crops Council**

**MS. SPAGNOLI: Julie Spagnoli, Bayer Health Care**

**MS. BROWN: Amy Brown, Pesticide Education Safety Program, Professor at the University of Maryland representing Win Hock.**

**MR. ELWORTH: Larry Elworth, Center for Agricultural Partnerships.**

**MR. NICHOLSON: I'm Erik Nicholson with the United Farmworkers of America.**

**MS. McKINNON: Lori McKinnon with the Yerok Tribe and Tribal Pesticide Program Council.**

**DR. KAWAMOTO: Melody Kawamoto, Center for Disease Control and National Institute for Occupational Safety and Health.**

**DR. TROXELL: Terry Troxell, Food and Drug Administration, Center for Food Safety and Applied Nutrition.**

**MR. JONES: Jim Jones, Director of the Office of Pesticide Programs, EPA.**

**Before we get into the agenda, I just wanted to say a few things. This is, as we all know, the Pesticide Program Dialogue Committee, which is a Federal Advisory**

**Committee. The Federal Advisory Committee Act is a law that governs how the government interacts in the context of getting advice from stakeholders, and it has a couple of provisions that are important: that we give notice, that there will be a broad group of stakeholders, and that we post our agendas. Basically, we are trying to ensure that the government gets advice in a fair manner that's not behind closed doors. And so, over the years, we have tried, sometimes with great success, sometimes with less success, to get advice from the PPDC.**

**One of the things that we have learned over the years is that to get good advice you really have to work at it and prepare in advance for it - and that goes both for the agency and for the members of the PPDC. When we just come to you with an issue and ask for you to respond to it (on-the-spot and in the moment), it's very hard for us to tee the issue up because the issues we're looking for advice tend to be pretty complex. Otherwise we wouldn't be asking for advice.**

**It can also be hard for you because you may not**

**have enough information in advance to give good advice. So one of the things we've begun to do over the last year or so -- last couple of years, is to work more aggressively to tee up the issue so that we can get more thoughtful, more involved, better advice from the members of the PPDC.**

**I think that you will see that play out in a couple of areas here today, two in particular -- that being Animal Testing which actually is this afternoon -- and Registration Review, where we've engaged pretty aggressively over the last six months to a year depending on the topic, to work with members of the PPDC to identify what the issues are, to work through the issues so that we can get some real thoughtful, meaningful advice that we can then chew on and make choices around.**

**And I think that we're committed -- I know we're committed, as I'm committed to the Agency sustaining this enhanced activity around the PPDC meetings and not just being at the PPDC meetings. But for it to work, we're**

**going to need for the members of the PPDC to sustain their involvement, not just at the meeting but between the meetings. Actually, I think some of the real meaningful work goes on between the meetings as we saw in the non-animal testing and we'll see this morning in the registration review.**

**I just wanted to take some opportunity to remind us all about why we're here and what it really takes to give meaningful advice> And it takes a commitment on our part to give you all the information in a meaningful way that usually involves more than just a presentation in this meeting. It involves you engaging in between meetings in the various forum that we create for that. And that doesn't mean you have to, as an individual member, participate in every one of the activities that we have going on, but I think it is important that every one of you participate in some meaningful way in some of the issues that we're working on.**

**And so, just sort of a reminder -- and it is a little bit of a shift in our paradigm, and I think it's a**

**shift that's come about from feedback that we've gotten from all of you and from just the general learning experience on our part about when we're most effective is when we work these issues throughout the year and not just at these meetings.**

**I also just want to remind folks that we -- back in our last meeting we talked about -- I talked about how we like to structure this meeting and there tended to be a fair amount of consensus around this. We like to spend some part of the time just debriefing you on activities within the program. I actually like that to be a lesser part of the time, not a full one-third of the time. And we have a few places on the agenda - where we're going to be debriefing you. Endangered Species is certainly one of those, as well as some of the general updates that we have scheduled.**

**We're going to spend some of the time on what I consider to be accountability reporting -- where we're going to report on things that this committee has already taken up at a previous meeting. I don't think it's**

particularly satisfying to just give advice and then, never hear about what happened to it. I think it's important that the Agency come back and say here's what we're doing around the advice we got on that last issue we talked about six months ago or a year ago. And we have some things on the agenda, certainly, that fall into that category.

And then the last category are teeing up issues that we want to get feedback on from the PPDC for future work, and I think we have a session along those lines that we've revamped as well, but I'll talk about how we revamped it tomorrow when we get into that session.

So, with that I would like to turn it over to a follow-up issue. I'm hopeful -- this is follow-up regarding registration review. I'm very hopeful that we, in this topic on this dialogue committee -- not just meaning this meeting, but in subsequent ones -- we can really in this area, registration review, create a model for how the Agency gets advice before it launches a new program that just doesn't involve notice and comment rule

**making. It involves getting meaningful stakeholder advice. Meaningful stakeholder advice before we launch into writing a draft rule, and that's the registration review area.**

**And before I turn it over to Betty and Jay, I think a couple of folks have joined us since we did introductions. If you could, just identify yourself and your affiliation right now. Bob**

**MR. ROSENBERG: (Inaudible) -- Bob Rosenberg.**

**MR. JONES: Well, you know, Bob, I do like to say -- not to embarrass anyone, you know. You want your registration and your regs on time, you got to start your meetings on time. Sorry.**

**MR. ROSENBERG: Bob Rosenberg, National Pest Management Association.**

**MR. VAN DUYN: Gerret Van Duyn, National Cotton Council, sitting in for Bill Tracy.**

**MS. ROBERTS: Amy Roberts, Technology Science Center, sitting in for Gary Libman.**

**MS. BRIGHT: Patti Bright, the American Bird**

**Conservancy.**

**MR. McCORMICK: Bill McCormick, Clorox.**

**MR. KELLNER: Steve Kellner, Consumer Speciality Products Association.**

**MR. JONES: Okay. Very good. With no further adieu, Betty and Jay.**

**MR. ELLENBERGER: Good morning. Again, I'm Jay Ellenberger and to my left is Betty Shackleford, and we're going to open up the first topic this morning, Registration Review, and share with you some, I think, very fine work that our work group has put together -- a set of recommendations on three important issues for the Agency, as the Agency moves forward on planning and developing its registration review program as required under FIFRA (phonetic).**

**Just a little bit of background first. If you look at the first slide, I'm going to introduce a little bit of background of registration review for some of you who may be new to this group or just need a little bit of refresher since the last meeting in April when the Agency**

**did put together a presentation of registration review and some of the issues on it was thinking and grappling about, which led to the formation of this work group.**

**But very briefly, this was our reminder. FIFRA provides for a periodic review of pesticide registrations and the goal is to do that about every 15 years. In other words, to look at all the pesticides that are licensed for use in the United States and reassess them in a manner. The Agency is supposed to do that by establishing a regulation. So there is a procedure that's open to the public and clearly vetted about how we go about doing that. And if the Agency would use data calling authority, as well as all the other authorities under FIFRA to do whatever it needs to do to do that registration review assessment.**

**In April of 2000, the Agency did publish an advanced notice of proposed rule making on this, asked for public comments. We did receive some and those were discussed, again, at the April meeting. But it provided EPA's initial ideas and concept about how we would go**

**about this new program.**

**At our April meeting there was enough interest, not only by the Agency, but by the PPDC to work this issue further, and so Jim Jones charged that this work group perform, which it was in June of this year. Next slide.**

**If you look at the second to the last page of your handout, you will see a list of the 23 group members for this workgroup. We got a lot of volunteers when Betty and I sent out an invitation to PPDC for interested individuals, organizations to play in those, and we initially thought there would be, oh, perhaps 10 or 12 people stepping forward, but we got 23. And you'll see that it's a very good diverse mix.**

**We have representatives from large registrants, small registrants, crop and user associations/organizations. We have other Federal Agencies, State Agency representatives, Tribal representatives, Environmental Advocacy organizations. I think it's a very well balanced group. As we went through**

**the meetings this summer, we felt that we really did get that, kind of, balanced input. It was very good.**

**Over the summer we did hold a series of four meetings to discuss three very important issues that we teed up to get recommendations. The three key issues were the criteria for scheduling registration reviews for all the pesticides. The enormous task of figuring out what's the order -- what makes sense. So we looked at a number of issues there, a couple different options, and we'll talk about those.**

**And then the second issue is should there be different ways of reviewing pesticides. In other words, not all pesticides have the same level of risk, the same kind of use patterns, so on and so forth. Should there be some tailoring, if you will, for each of the pesticides that will be going through registration review.**

**And then thirdly, a very important issue, what should the stakeholder participation process be.**

**As we discussed those issues -- next slide. As**

**we discussed those issues, we couldn't help but, sort of, bringing out a couple other very important related issues that we're also going to talk about today. What constitutes a registration review? What does that mean? How do we ensure that a registration is kept up-to-date so that when it comes ready for registration review the Agency has everything in order and the public, who wants to participate in that review process for that pesticide, also can keep up-to-date and wouldn't have to start from scratch, so to speak. This would help make a much more efficient process. And then how do we deal with inert ingredients, which, of course, are in all the pesticide products. How do we deal with that?**

**So, the way we would like to construct the presentation this morning is we will have a number of panel members from the volunteer -- from the work group give presentations for each of these issues.**

**First, we will have Sue Crescenzi, representing Steptoe & Johnson, who represents a number of the smaller and larger registrants, who will be talking about**

**scheduling or issue number one. Followed by Julie Spagnoli of Bayer, obviously representing large manufacturers. She'll be talking about issue number two, or the levels of review issue. And then Therese Murtagh from USDA will talk about issue three, or the public participation process.**

**Patti Bright, from the American Bird Conservancy, will also talk about some very broad recommendations that, sort of, are overarching for these issues. And then Ray McAllister will follow-up with a discussion of these three additional issues that the work group discussed. And then we'll open it for -- to the full PPDC for follow-up discussion.**

**So, Betty and I, first of all, would just like to thank the work group. It worked, I think, marvelously. Great participation. A lot of cooperation. Worked very well together. We did not try to reach consensus on every issue. I think that was the beauty of it. We didn't have to twist arms or anything. It was, sort of, a free flow of ideas and information. As a**

**result, I think we got a very good product out of it.**

**So, with that, I would like to turn it over to Sue Crescenzi for issue number one.**

**MS. CRESCENZI: Okay. This is working now? Okay. We knew that in scheduling this program with the statutory goal of 15 years to actually make it through all of the chemicals would be a real challenge given the fact there are currently about 1,200 active ingredients registered, 20,000 unused products registered. This changes over time and there will be additions, deletions.**

**So that was our first challenge. How do you come up with a program that will work given these numbers? And we also recognized that there were, perhaps, opportunities for doing some combinations given that there are some chemically related families and that they are sometimes treated together.**

**We discussed a number of alternatives. I think in our first meeting we very seriously discussed the concept of worst first. But I think as we went along and as will be reflected in the other presentations that you**

**hear, we ultimately concluded that we were going to be best served by sticking pretty closely to a chronological schedule and there are a couple of reasons for that.**

**We thought getting into complex scheduling would get us into areas of great subjectivity that could become controversial, and also that kind of process is resource intensive and time consuming, and we really want the maximum amount of effort in the registration review process then on substantive and not administrative. And as will be discussed -- so we said, okay, we need a predictable schedule that can be published and updated as necessitated so that everyone knows essentially what the order is, when things are likely to come up. And the importance of this, I think, will be highlighted, too, in the discussion about public participation. In the 15 year the chronology would be based on primarily the registration decision or the re-registration decision.**

**We talked about the fact that there would be some instances where there would be a need for departure from that chronological schedule. I think it was the**

**strong consensus of the group that there should be fairly specific criteria that would have to be met in order to support a reason to change the schedule from chronology, and that we wanted this established in regulation. I think it is fair to admit that our colleagues from EPA were totally not thrilled by that particular recommendation, but again, I think the group thought that was necessary so that you didn't end up with a meaningless schedule that was constantly subject to change.**

**The plan would be to publish this comprehensive schedule in the Federal Register, as well as on EPA's website, with updates as appropriate or as regularly scheduled. I mean, those are some details that we certainly haven't worked out. That way every one -- every stakeholder with any interest in this process will have the ability at any time to see what the schedule is and to project what their timing needs to be in order to prepare for the various stages through the process.**

**MR. ELLENBERGER: Thank you. Julie.**

**MS. SPAGNOLI: In looking at the levels of**

**review, as Jay mentioned we recognize that not all chemicals pose the same profiles -- that various chemicals may have different risks, different use patterns. In the discussions of the work group, we quickly identified the need to not have a one-size fits all type of approach. That this would, you know, over -- there would be too much resources put on things that didn't need to be or conversely not enough resources put onto those things that should have more attention.**

**So, we wanted to look at, you know, that the scope of the program would make the most efficient use of resources. There was a lot of talk of finding the easy off ramps for those chemicals that didn't require an in-depth reassessment.**

**We also looked at what kind of inputs would go into those kind of decisions and there would be changes in data requirements or adverse effects, policies. What would change during the course of 15 years with the registration that would warrant a reassessment? If nothing had changed or if there were no concerns raised**

**with the chemical, then we wanted to make sure there weren't undue resources put towards assessing things that didn't really need to be looked at.**

**So, what we had developed -- this is going to be better, much better if you look on -- I think there's a full page picture in the packet. Yeah. Page 10.**

**MR. ELWORTH: This is an early re-registration --**

**MS. SPAGNOLI: Well -- and again these kind of flow charts always look very complex at first.**

**MR. ELWORTH: This doesn't look complex at all.**

**MS. SPAGNOLI: Okay. Well, thank you, Larry. They look complex at first viewing because it looks like like you see a lot of boxes and a lot of lines. But what we were trying to do is look at decision points along the way and this was -- and I think they're going to send this out electronically and you can see it in the color.**

**But looking at points where questions could be asked, starting with, as we noted, a Federal register**

**notice to announce the initiation of the review and solicit stakeholder input. Then asking the question are there new uses or significant changes. If no, then ask if there is new data or new adverse effects or new standards. If no, look at individual registrations for deficiencies, and if there are none, then we're done. This is the easy off ramp approach.**

**Again then if there are questions that need to be asked regarding the assessments; looking at the assessment; are they current; if they are, are they acceptable. Again, there's an easy off ramp. But if there are questions raised and there are significant issues, then it goes into the system of looking at the -- you know, redoing a new assessment, getting inputs necessary, doing mitigation if necessary. If it can't be -- you know, if the risks are not acceptable, then either canceling uses. It would go through the regulatory process of initiating, cancellation of uses, either voluntarily or not.**

**Risk benefit assessments would come into play if**

**risks -- if there were uses that looked to be of unacceptable risk.**

**In the case of individual registrations, if there are -- data are necessary. If there not, compliance with the data requirements or a registrant chooses not to comply with data requirements they can elect to cancel.**

**So, again, looking at just a way to make the process flow as efficiently as possible.**

**And I guess this is just an over review. Again, we look at the registration review process to look for streamline reviews for simply -- as we call it, simple pesticides. Look at also streamlined process for pesticides with a stable regulatory history and science. If nothing has basically changed in 15 years, we don't want to spend a lot of time looking at it. And then again, with pesticides with complex issues would require a more robust assessment. So, again tailoring the review to the needs for that particular product.**

**MS. MURTAGH: The third issue that we addressed**

**was the need for meaningful public participation throughout the process and the group agreed that the process needs early participation from all stakeholders. We also agreed on the importance of a predictable schedule and this, sort of, echoes what Sue was saying -- the importance of the schedule so that stakeholders can prepare for and participate in re-registration review.**

**In addition, we agreed on the need for an understandable process where the opportunities and the expectations for public participation are very clear.**

**So, our recommendations are that stakeholder input would be sought. And you can see that -- those opportunities are on the flow chart that Julie discussed. So, they would be at the junctures that are identified on that flow chart, so that there would be stakeholder input on use profiles, risk assessments, risk benefit analyses and risk mitigation measures.**

**The stakeholder process should be tailored to the level of review. So, the larger the review, the more comprehensive the review, the more stakeholder input**

**would be sought and needed.**

**We also agreed that modern electronic technology needs to be used to help facilitate the stakeholder access to information. The group recognized that EPA currently uses -- you know, has some excellent tools that they're using for their e-docket right now, but we think that that could be strengthened and that this -- the e-docket should be expanded to provide a continuum of information and that would include the active ingredients history, its status. It would include all the public comments and previous regulatory decisions on a pesticide.**

**We also recommend that the Agency publish a Federal Register Notice to initiate each chemical specific registration review.**

**MS. BRIGHT: These are some of the general recommendations that the group came up with. Some of these things have already been discussed by Therese and Julie and Sue. We decided to, kind of, bring them together at the end. We felt that these were, kind of,**

**the take home message. These are the things that we wanted most out of this group.**

**So, to begin with we felt that the registration of the chemical is not static. It's important to recognize that issues, big or small, can and should be addressed as they arise. The registration should not, in any way, supercede EPA's authority under any other provisions of FIFRA. For example, data call-ins, special reviews, suspensions, cancellations, et cetera.**

**The second recommendation that we had was that registration review should always be considered as a safety net and we feel that this is a really important concept and this is, kind of, the concept that the working group continued to keep in mind as we went through some of these issues.**

**The idea of the safety net is to ensure that there are no administrative deficiencies and to ensure that all products are periodically evaluated and are in compliance with current standards. So, as Jay said, this would be done on a 15 year schedule. Registration review**

**is intended for EPA to review existing registrations in a timely manner in accordance with the procedures established by regulation.**

**Our third recommendation was that we felt that in order to maximize efficiency the degree of reassessment necessary should be determined by a decision based process. So it should not be a one size fits all process, but rather it should be based on stakeholder inputs and the applicability of existing assessments.**

**Next slide. Our fourth recommendation was that we felt that the registration of use schedule should be updated either annually or, perhaps, biannually to account for variations in EPA's yearly work load, so to, kind of, even things out.**

**We felt it was important that a Federal Register Notice should be published to announce any updates to the schedule. Next, we wanted to ensure that there was -- to ensure that there was broad public participation in the registration process. So, we felt that the schedule should be published on the EPA website and that should be**

**published well in advance. That would ensure that stakeholders would always know where to find it.**

**And then our last -- excuse me. Our almost last recommendation was to ensure that data is submitted in a timely manner and therefore, we wanted to have EPA -- and to have EPA have adequate time to review it, we wanted to make sure the schedule was a predictable process so that stakeholders would know early on when they should submit data.**

**And then finally, in order to ensure the review of chemicals with outstanding issues, such as data call-ins, et cetera, would be completed in a timely manner, we felt it was important that EPA should implement some kind of mechanism. So, for example, if there were a data call-in and a registrant did not submit the data or chose not to, that there would be some mechanism for completing the registration.**

**MR. McALLISTER: There were some additional issues that came up in the discussion, which are not totally resolved and would become part of the discussion**

**in developing a rule, as well as implementing a program of registration review.**

**Obviously, we need to understand what constitutes a registration review decision. How do you know when you're done with the process for a given chemical? A key part of this decision was whether or not a pesticide meets the requirements of FIFRA 3(C)(5) in terms of no adverse effects.**

**The potential outcomes -- there are several potential outcomes on a registration review. If it meets that standard and there are no questions about it, no remaining data gaps, then, obviously, you can say registration review is done.**

**Registration review might occur for a given chemical when there are outstanding data requirements, a DCIM progress, or the review itself might discover or turn up additional data that need to be updated or provided for that chemical.**

**Those situations bring up the question does one defer a decision on completion of registration review**

**until the data come in, or the fact that the studies are in progress, does that satisfy the registration review.**

**Also, if the determination is made during registration review that the product does not meet that standard, then either mitigation needs to take place or the cancellation proceedings would take place in accordance with FIFRA Section 6.**

**Fifteen years can be a long time in the life of a pesticide product and how does one ensure that a pesticide's registration is kept up to date? The law, itself, in FIFRA Section 3G specifies that the registration review does not take the place of or prevent EPA from conducting any other review of a chemical, and there are a number of situations and processes by which EPA can initiate and continually review a chemical, whether it's special review or new data requirements or significant changes to existing data requirements.**

**EPA continually monitors the adverse effects information submitted under FIFRA 6A2, and if that turns up significant concerns about an individual chemical,**

**those concerns should be handled on a timely basis and certainly would not be delayed because registration review doesn't come until several years down the road.**

**So, those reviews that happen outside of the registration review process may address significant portions of the overall package for a chemical, whether its occupational exposure, residential exposure, dietary exposure. The registration review becomes a safety net to make sure all of those aspects for a given chemical are handled at least on that 15 year cycle, as well as to address any compounds which otherwise have not come to the attention of the Agency for other reasons.**

**Inert ingredients, in and of themselves, are not registered by the Agency, though they are regulated. Because they don't specifically fall into the registration review program, we collectively, as stakeholders and as EPA, need to find a way to account for them in the registration review process because we have to review the registration of individual products, which contain those inert ingredients, as well as all the active ingredients.**

**I think there's a lot of work and a lot of discussion yet to determine how that would happen.**

**If you look at your chart on page 10, the key box is in the upper right hand corner where it asks the question are assessments current. This is on the next slide.**

**So, a key question here for the registration review process is what constitutes a current assessment. Some of the criteria you would consider in terms of dietary assessment. It would certainly have to include all food uses then registered at the time of registration review; for other assessments that are not dietary, such as residential exposures, ecotoxecology, endangered species concerns, or occupational exposure -- would have to consider all of the relevant uses to each of those scenarios in times of assessments.**

**Additionally, one would have to consider that there are no indications of significant new or increased adverse effects through the 6A2 reporting system. Thank you.**

**MR. ELLENBERGER: That ends our -- concludes our work group presentation. So, I would like to turn it back over to the PPDC.**

**MR. JONES: Thanks, Jay and Betty. I think that this group did just what we asked them to do, which was to give us some -- give the PPDC, actually, technically -- they're giving this committee some advice for PPDC to chew on and decide whether or not you would like to make some recommendations to the Agency.**

**So, I think it would be useful at this point to open it up broadly to the committee for questions and thoughts. Bob.**

**MR. ROSENBERG: Well, just -- I'm sorry. Well, I guess, two-and-a-half questions and I think it's for Sue. When does the process start? Is it after tolerance reassessment?**

**MS. CRESCENZI: Actually, you know, we didn't -- we didn't get into that. There are -- technically we should already have started and obviously haven't because there's no -- there's no regulatory process in place. So,**

**I guess, it starts on the day it's ready. I mean, I would defer to the EPA folks on that, but I don't --**

**MS. SHACKLEFORD: Sure. I can take that one, Bob, if you don't mind.**

**MR. ROSENBERG: Sure.**

**MS. SHACKLEFORD: Some of us have had this near and dear to our hearts for a long time. What's envisioned by the Statute is that there would need to be implementing regulations in place before the Agency would be able to make decisions under the quote/unquote registration review program. We've considered that to mean that we can initiate work on chemicals prior to having those implementing regulations in place, but the decision making under that umbrella couldn't occur until they were established.**

**MR. ROSENBERG: Understood. And the reason I'm asking is from a, kind of, scheduling and resource point of view, I mean wouldn't it, sort of, make -- I mean, I'm assuming this is an SRRD function. But I guess that's not -- I mean, maybe it's not.**

**MS. SHACKLEFORD: We haven't heard.**

**MR. ROSENBERG: Yeah. I don't know, but I mean I guess -- if SRRD is preoccupied with tolerance reassessment, it would kind of seem like that would be, sort of, the natural transition would be to go from tolerance reassessment to registration review.**

**MR. JONES: That's right, Bob. I think programmatically what we would like to do is have in place the regulations so that when we finish tolerance reassessment on August 3rd of 2006 we segway right into on the 4th, registration review. But I think Sue and Betty gave the right answer. You want those regs in place before August 3rd of 2006.**

**MR. ROSENBERG: Got it. Well, then, my second question, and I think this came up in the initial discussion, was -- and I think that it makes a lot of sense on what we're talking about -- that it's chronological based on registration and re-registration decisions.**

**But there was a question that came up in the**

**initial discussion back when we first discussed this about what if you have -- let's say the first product in line is something that first got registered in 1984, but it's in the same class of chemistry as something that didn't get registered until 1992. Do they get lumped together and sort of get taken out of order, or do you stay with the chronological process?**

**MS. SHACKLEFORD: Well, that -- again, there was a fair amount of discussion on that and I think that everybody was of the opinion that where it made sense, and particularly if chemicals relied on primarily a common database and that kind of thing, that even if you had a new registration, that that -- that would be the kind of criterion that would allow you to move that chemical in with the other group.**

**You know, we had a lot of discussion about that and we haven't -- you know, I can't say that we came up with every particular criterion that would be -- allow you to move it, but yeah. I mean, where it makes sense and certainly where -- the one I'm familiar with are**

**quadernariumonium (phonetic) compounds. And if you register a new quad it doesn't make any sense to deal with that quad on an individual basis despite its data registration. It should be moved in with the group itself.**

**But there are going to be issues that are a lot greater than that, and I can't say we figured it all out. That, again, is where EPA wants, pretty much, clear flexibility and the work group said no, the criteria --**

**MR. JONES: That's a very logical example you gave. Did the work group have other examples that they would want the Agency to consider for going with other than a chronological schedule?**

**MS. CRESCENZI: Well, I think what we looked at was where chemicals shared a database because, again, the review is not to do an -- it's not to say, okay, if we have a concern with a whole class of chemistry we wait until, you know, 15 years or wait until one of them comes up for registration review. This is, again, that safety**

**net concept of looking at that chemical and its database and are there any deficiencies, are there any issues specific to that chemical.**

**Now if, again, there's a class or a group of chemicals that share a database or share, you know, specific -- you know, all of the use information, then it would make sense. But, I think when we're looking at an individual chemical and what possible deficiencies it has it makes sense to do them individually and make sure that each of those chemicals has been kept up-to-date.**

**And, again, that doesn't say that if an issue is raised with a class or a whole group that that's not addressed before registration review or outside of registration review.**

**MR. JONES: Bill.**

**MR. McCORMICK: Thanks. This is a very nice presentation. I think there's been a lot of good thought put into this. I've got two questions.**

**One is in doing this flow chart and thinking about the issues that the Agency may have information**

**and also public input, Federal Register Notice, did you scope an approximate time it would take to do an individual registration review? And if so, do you back off and say you started your 10 and, you know, there's going to be data gaps that need to be generated so you can complete at 15, or does the 15 year start the clock and it just goes forward?**

**So I'm, sort of, wondering about timing and process. And then I have a second question.**

**MS. CRESCENZI: I can answer some of that. I think one of the things that we talked about was having the predictable schedule with a clear understanding of when something was anticipated to come up and also having a process built into the regulations, again so that people understood where the input points were, whatever, that we thought the ideal would be to arrange it in some way where information that -- that would not be subject to a -- you know, not data call-in information because, obviously, the Agency hadn't looked at it. But changes in use and use information.**

**You know, compilations of adverse effects that people are concerned about, whatever. That they would be made available at a point in the process so that, at least, that EPA, perhaps on the day that the review was announced, that would be the deadline for getting in that initial --**

**(End tape one, side one.)**

**MS. SPAGNOLI: Well, I think it comes back to the level of assessment.**

**MR. McCORMICK: I realize that.**

**MS. SPAGNOLI: Obviously the more robust the reassessment or reevaluation needs to be, the more time consuming it will likely be. But I think some of the questions that we raised at the end -- you know, what constitutes registration review decisions. Those will, kind of, impact some of that because if a registration review is complete or considered complete after it's been reviewed and let's say we have identified some data gaps and the data has been requested.**

**If at that point it's considered the review is**

**complete, then obviously the time frame is shorter. If the review isn't complete and those data are generated, submitted and reviewed, then obviously it becomes a much longer time frame.**

**MR. McCORMICK: I'm going to keep drilling. There was no discussion like, well, if it was really easy and -- there were no controversies and it was, you know, review light and you still went through this decision making process it might take six months; if it was a heavy review it might take 18 months, two years or something like that. There was no kind of time frame.**

**Because I'm wondering -- I mean, ultimately you have to make these decisions, you know, and you start talking about scheduling anticipation of things, and doing this in a 15 year time period, there is a time element of the process that needs to be considered in order to make it happen. I just wondered if there was any deeper discussion beyond identifying the facts about actually assigning times.**

**MR. ELLENBERGER: No, Bill, there wasn't. That**

**wasn't -- that's an excellent issue. We didn't start with that as one of the three main key issues. But we did talk a little bit about the need for efficient process because recognizing the 1,200 active ingredients currently on the list, so to speak, that works out to about 80 a year.**

**MR. McCORMICK: Right. Okay. Well, that --**

**MR. ELLENBERGER: So -- which is daunting. So, figuring out how to do that as efficiently as possible. So we didn't get down to your question, well, what would it take -- was it five months, six months, 18 months, whatever. But that's an excellent issue that has to be looked into.**

**MR. McCORMICK: And the reason that I bring it up is, you know, we're currently working in the antimicrobial**
**division on trying to get a lot of these actors reviewed on a very short time frame and people have put up very aggressive review period times, which probably aren't really all that practical.**

**And so, I would advocate that if we're building a process we don't make false times that really -- is it possible to do this in 30 years, you know, much less than 15, you know.**

**So, somehow if the timing is driving the process to an extent and you really have to turn 80 a year, the process has to be capable of 80 a year, with whatever degree a complexity is required.**

**Second question -- do you want to respond to that?**

**MR. ELLENBERGER: Yeah. We would anticipate, you know, speaking from the industry prospective, that these registrations -- we're not going to find large defaults in terms of data needs. We anticipate that the Agency and the registrants are going to keep those registrations close to up-to-date on a continual basis through other review mechanisms, and that this is -- hopefully, for most compounds it's a checklist. You know, you've met all these requirements. You can perceive that we've checked everything off.**

**Obviously there are going to be some where you discover additional needs and it's probably at the beginning of a review -- registration review process for a given compound that you can decide how close you are to complete. So, it may not be until that comes up for review that you can decide this is going to be done in three months, or this is going to take 18 months.**

**MR. McCORMICK: I know, it's problematic, but -- we can move on. My other --**

**MR. JONES: Carolyn, did you have a question on the first point that Bill had made or --**

**MS. BRICKEY: I don't have a question. I have a comment.**

**MR. JONES: Okay.**

**MS. BRICKEY: I just think that if we really did not get into the heavy duty issues, like what kind of -- how are you going to decide what level of review to conduct and -- you know, the decision is made when the chemical meets the standard.**

**But it almost sounded like yesterday when we**

**talked a little bit about this, we were getting into a red light process where you would have also a decision point that the review is done. You know, like it would be a two-step process. A, the review gets done. That means we know everything. We've done an evaluation. We have a red in effect. And then, two, the decision gets made that it's met the standard.**

**So, I think maybe you can, kind of, frame a process around that. I don't know what the other members of the group think. That's what I was thinking last night after our discussion.**

**FEMALE VOICE: And just to pick up on that -- is Jay here or Erik here?**

**MS. BRICKEY: Erik is not here.**

**FEMALE VOICE: Oh, okay. And this is to express one of Erik's concerns and that is -- and you tell him I did this.**

**MS. BRICKEY: I'll tell him. He won't believe me.**

**FEMALE VOICE: But there was discussion about,**

**well, don't you at some point have to make a decision and doesn't that decision have to be made in some kind of time, or timely manner. And we got hung up for a while on the whole issue of special review. If, as a result of this review process, the chemical goes into special review is registration review completed only at the time that there is a final decision and special review, and we know that those can go on endlessly.**

**So, I can't say that we really came to -- I don't know if the red light and then you -- you know, we just -- there's disagreement as to whether you can say the registration review is completed before the 3(C)(5). Yes, it still meets the 3©)5) criteria. You know, we're not there. We didn't -- that was something we were still working on.**

**MR. JONES: Why don't we go back to Bill and then to Larry, then to Allen and then to Julie.**

**MR. McCORMICK: And my second question maybe is direct to you, Jim, or to the group also was -- was there any discussion of places, you know, where this is going**

**to reside? Specifically, I'm thinking about when there's reviews done on BPPD or antimicrobial division, which are divisional decisions versus SRRD. Was there a discussion among the group about any differences among those divisions and how this would be handled?**

**FEMALE VOICE: I don't think we really saw that as part of our -- we were really just looking at process and procedure. I guess if you wanted to have that process and procedure in all three divisions or all in one. I don't think we really -- we were looking more just procedurally and --**

**MR. JONES: I would -- certainly at this point, and I would, knowing myself, predict that that's not something I'm going to be interested in stakeholder advice on. I think that's where we are going to be much better situated to figure out how to do it, but -- people change.**

**But I, at this point, certainly wouldn't ask the stake -- the committee to focus on how internally we manage ourselves.**

**Okay. Larry.**

**MR. ELWORTH: A little bit on the genesis of how this came about, which would help, I think, inform us. This was legislatively part of the genesis. The reason for doing this was having gone through re-registration. The question was, okay, what do we do now assuming -- you know, when re-registration and tolerance assessment was done. And the interest was to make sure that we didn't create yet another huge backlog because it wasn't a regulatory mechanism to look at pesticide registrations on a regular basis.**

**There was a deliberate decision not to go with a registration sunset provision. I mean, there were some deliberate decisions here that -- at least what would pass Congress.**

**It also was not meant as a substantive for any of the existing regulatory mechanisms. I mean, as you were talking -- I mean, there's always the opportunity for the Agency to do a DCI on a set of chemicals for which it has some concerns. I mean, it's not meant to short**

**circuit or subplant any of those.**

**It's also not meant as, kind of, a continual improvement program or as, kind of, a regulatory limbo or perpetual health for registrants. It wasn't intended as any of those things. It may end up turning up that way, I mean, but -- turning out that way. But it was meant to provide a mechanism so that we would look at these things on a regular basis and make sure that the science and the information are up-to-date so we don't recreate 20 years from now re-registration two.**

**I have two questions, though, that you may want to address, Jay, that are kind of more from the Agency's point of view. One is if you could talk a little bit about what the next steps are for both the work group and for the process of coming to the point where you have a reg on this. And the other question is to talk a little bit about the options that the Agency is looking at to get the resources necessary to do this.**

**MR. ELLENBERGER: Well, the next steps would be for the Agency to draft and publish a proposed rule on**

**the process as required by FIFRA and we would like to do that in 2004. I don't have a specific schedule right now to share with you all.**

**But obviously just from just a little bit of discussion and the work group discussion, a lot more thinking needs to go into specifically what that proposal would say, but also keeping in mind what we had said in the ANPR in 2000 and the comments that came in from that, the recommendations from this work group and PPDC, and it's sort of the question of whether or not this work group or a similar one continues to give advice to the full PPDC and the Agency as we work through that whole process.**

**But, answers are --**

**MR. JONES: Let me add to that a little bit. So, for the rest of the dialogue here folks have a general sense as to where we're coming from. As Jay mentioned, we would like to see this group continue to advise us, the PPDC and the Agency, as we develop a proposed rule. And right up to the point in which the**

**proposed rule is signed and is sent out for public comment, at which point we, sort of, have to step back and let the APA process take over and you submitted us a comment, we want to engage in this kind of dialogue, literally, as we draft the proposed rule.**

**So, as you're thinking about what advice you want to give us about next steps that might help you think about it because if you know a system is going to exist right up to proposal, you might not feel like you have to, you know, put a stake in the ground right now and say I really don't want this in it.**

**I think we're going to -- we're hoping to see, unless you all don't want to do that, collaboration where we're getting advice right up to proposal.**

**And the resources -- '06 will be an important year for resources around this and we'll need to use the process within the Executive Branch to be participating in an appropriate way in the development of the President's budget for '06, which doesn't happen for a little while.**

**Al.**

**MR. JENNINGS: Well, certainly have a predictable work schedule is an enormous positive thing for everyone concerned. But my question is how this can be reconciled with the Agency's mission to protect health and the environment? Should new information come to light about a particular product, how does it get promoted to the head of the class, so to speak, in terms of a reevaluation or an early re-registration? It's not hard to imagine that various stakeholders would have quite different opinions as to whether or not this should be done?**

**MR. JONES: Well, it sounds as if there was some discussion around that. Julie --**

**MS. SPAGNOLI: Yes. There was a lot of discussion.**

**MS. SPAGNOLI: Well -- and I think this really goes to what my comment was going to be anyway. In our discussions we made it very clear that this is not the process by which EPA takes an action against any**

particular chemical. It is not the catch-all of -- nothing is going to happen to this chemical until it gets into registration review. That the registration review does not supercede or replace -- this was one of Patti's points. Does not supercede or replace EPA's other authorities.

If there is a concern at any point or any time with a chemical -- and I think from a registrant's point of view, we know that registration of a chemical is never -- very -- or very rarely, unless it's one of these simple -- a stable static process. There's constantly issues that come up and are addressed throughout.

What -- again, we're looking at registration review and what this statute says is that they must -- you know, the Agency must periodically review the registration. That means they need to go back and look at it. And, again, we want to see this as the safety net.

We don't want to wait until then to address issues, but this would be the safety net to make sure

**that there is nothing that's been overlooked either administratively -- perhaps just that individual registrations, the label is out of compliance, or some major -- you know, if there was a risk issue.**

**We really don't envision that this would be the mechanism for a recognition of a huge risk issue. If there's a big risk issue it should, hopefully, have been identified before registration review.**

**MR. JONES: I'm sorry, Ray, I didn't realize your card was up. Then we'll go over to --**

**MR. McALLISTER: There shouldn't be a need to move a chemical to the head of the class. As Julie says, if a risk issue comes up it should be handled at that time in the appropriate mechanism outside of registration review. Then when registration review comes around you check the box that that's been done recently or update anything that's happened in the interim.**

**I just want to make one other comment regarding the scheduling question that was discussed a moment ago. You know, the obvious -- we were discussing one possible**

**obvious grouping where compounds share large portions of a common data set to support their registration. And this is just my personal opinion. It wasn't discussed in great detail in the work group, but another probable or possible grouping is the common mechanism groups.**

**In the process of tolerance reassessment when a common mechanism group is identified and then accumulative risk assessment is conducted, the -- as I understand it, those individual compounds have interim reds prepared until the time that the cumulative risk assessment is complete and then that becomes a red.**

**And that's all going to happen basically simultaneously for that common mechanism group and they'll still have a common 15 year starting date. So they, sort of, regulate themselves into a common cycle to handle the common mechanism groups.**

**MR. JONES: Good point. Sue, you had your --**

**MS. CRESCENZI: Yeah. I just -- again, I think that when we started out at the first meeting we were supposed to take a look at re-registration and what we**

**had learned from it, and on the basis of what we had learned from it, what we would recommend for this registration review process; and that was very clearly that we didn't want registration review to replace re-registration as the only way to look at an existing registered pesticide. That, you know, a large part of the success of the registration review process would be keeping the trains running on time, for want of a better word.**

**So that as issues arose they had to be dealt with structurally someplace else. I think that was the sense that we had. Now, again, that goes into the way you all organize. But I think that there was a general consensus among the group that the folks involved in registration review were not necessarily the ones who were going to be dealing with the fact that there was some huge new concern about adverse effects to a particular chemical with a particular use. You know, that that was going to have to be dealt with in a timely manner immediately and that that was not going to impact**

**what was going on with registration review.**

**MR. JONES: Jose.**

**DR. AMADOR: Jim, I'm siding with Julie. I know the mission of the two groups are different -- you know, the CARAT and this group here. But the members of CARAT that are not members of the PPDC -- they're a member of this committee. Is any provision being made to keep all the membership of CARAT -- particularly those that are not members of either one of the two -- informed as to what is going on? Will that be something that --**

**MR. JONES: Yeah. We try to when there's an issue that potentially crosses -- there's mutual interest. Just to try to give updates to one group versus the other, which we try to give people here enough data on autonomy assessments. Similarly, if we find an issue that this group is working on, we would update CARAT on that. This is a topic that could potentially fall in that.**

**DR. AMADOR: Yeah. I just want to make sure these are being considered.**

**MR. JONES: You've generally heard what we would like to do process-wise, which is to continue this exercise with this group as we develop a proposed rule and literally keep the work group intact giving advice. You know, I think one of the most helpful things is as you identify issues that really need to be addressed, the group then, sort of, takes those issues on, works them further, gives us advice and in the interim we'll be working on a proposed rule that we'll be willing to share with the group. And then ultimately we'll have to make some choices at the Agency and a proposed rule will come out.**

**Again, Jay said 2004. I don't think at this point I can give an exact schedule. I personally believe that we might lose a little time and have it later in '04 by working in this manner, but ultimately in the back end we're going to gain a lot of time because there's going to be more -- there should be more buy into what we're doing.**

**PPDC -- anyone want to -- we say out loud that's a good plan or -- I didn't want to take your silence for a**

**sense, but if I have to I will.**

**MS. BRICKEY: Jim, I think it is a good idea to work it through the group. I think it makes a lot of sense and I think you will gain some time on the backside.**

**I guess my question is what's the next step? Do you anticipate our group working through some kind of draft, or does your staff want to work through a draft based on our deliberations and then come back to the group?**

**MR. JONES: I expect two things. That we'll work a draft based on what we've heard so far. Meanwhile, the group keeps working issues that -- I think there are a couple issues you identified at your last meeting or last two meetings. They need, I think, a little more dialogue amongst the group.**

**So, we'll work a draft. You work some more issues. As more and more issues get to a point where you're ready to, sort of, say this is as far as we got it, whether it's consensus or not, we'll then work another**

**round of the draft, so the draft will expand as we get advice around issues that are identified.**

**MS. BRICKEY: That sounds very good to me.**

**MS. SPANOLI: Well, I think as we saw with this process as we work through the process and even as we came to some agreements, as you really, kind of, started to frame things identified then -- kind of the next issue, and I think that that will continue as we work through this and as -- I think that's why it was good to have the good. Then as the new issues came up you could, kind of, confront those.**

**And I think -- you know, we basically came to an agreement on the three issues. I think the approach for the -- the three main issues we were addressed. But in the process that's where these additional issues were raised and I think the logical -- you know, it's now that these new issues have been raised as to work those through with the work group.**

**MR. JONES: Okay. Larry.**

**MR. ELWORTH: When you talk -- when you say**

**draft, what I assume that we can legally do is come up with a draft that says here is what the process is that seems to make sense to us. Obviously, from an APA point of view, you can't draft a proposed rule or something that even looks like a proposed rule. I think you get pretty far down the road as far as the draft -- here's how we can see the process going.**

**MR. JONES: Well, we're exploring just how far we can go. I have an interest in going as far as the law allows in terms of sharing information. But we're exploring that with our attorneys. Bill.**

**MR. MCCORMICK: Yeah. I just want to reiterate that -- I think it's a great idea to keep going and keep working, but keep in mind as you start refining this thing that there are timing and resource issues. I don't know how you build those back into the process, but let's not create a process that can't work.**

**MR. JONES: That's a good point. Okay. So, this work group will continue to work and we'll be getting back with the members of the committee in short order with,**

**sort of, next steps. If there are other -- if there are people who are on the PPDC who would like to participate in this, you know, e-mail Margie and she'll make sure that you get on the group.**

**Just as a note of caution for all of us, that what we're getting is advice and I will say at this point I think we're getting some very good solid advice. When we started to tackle issue number one, you could just see how hard -- you could go around on it forever. And having people from diverse perspectives come up with a recommendation around it has already, I think, saved the Agency a fair amount of time. It's the kind of thing you can spin your wheels on for a long time.**

**We're getting advice. At the end of the day, the Agency has to make choices and we will do that, but I don't want any of us to get confused that as we've turned over the program to stakeholders to develop, we have asked stakeholders to give us advice on how to do it. The farther along we get we'll probably run into some disagreements where the Agency is going to have to take**

**them back and, sort of, make a choice, and we'll do that.**

**But that being said, I think we're off to a very good start. I want to thank our Co-Chairs, Betty and Jay, for their hard work on that and thank, again, all of you for your participation -- participation, in particular, between the last meeting and today, as well as your participation today.**

**So, I think we are ready for our morning break and we'll get back in -- let's say 10:30, and hopefully we'll be ready then to roll on endangered species.**

**(A brief break was taken.)**

**MR. JONES: I'll just briefly introduce -- actually I'm just going to brief and say a few things about this topic and turn it over to Anne Lindsay, who is going to lead the discussion here.**

**Endangered species, as most of you probably know, has been an area that has been front and center with the office of Pesticide Program in the last couple of years, and it poses, what I feel, is perhaps the most significant management and programmatic challenge that**

**the office faces right now, which I think many people find that to be interesting as I think that they still think that our tolerance reassessment work poses the biggest challenges in those areas.**

**I hope to think that I'm thinking a little farther ahead and when I do that I feel like tolerance reassessment we, sort of, got our arms around it and it's about cranking through the work now. Endangered species, I feel, is an area where we still have a lot of work to do to fully get our arms around how we are going to successfully implement just that share of requirements.**

**I also think that many people in government in jobs like ours are reluctant at this point to talk publically about where they are because they haven't figured it out yet, and I think that one of the things that we have learned in OPP from our work in the PPDC and in the CARAT is that it is important to talk to people before you have figured it out, and in doing so, hopefully, you will get advice -- you will learn things you otherwise wouldn't have learned.**

**And so this is going to be -- in this forum, I think the first time we've really, sort of, spent a meaningful amount of time talking about the context surrounding endangered species -- what we know, what we don't know about our program implementation and we're going to have some dialogue around that as well.**

**So, with that I'll turn it over to Anne Lindsay.**

**MS. LINDSAY: Okay. What I'm going to actually try to do for the next almost two hours is be the moderator of, I think, actually a relatively large panel. The first portion of it will be a series of different government presenters, some of whom you all are very familiar with and others you may not have met -- not only from EPA, but also USDA, National Marine Fisheries and Fish and Wildlife Service -- so that you get, sort of, the full spectrum of the Federal Government prospective on pesticides and endangered species.**

**And then we will follow it up with -- I call it a non-government panel with four, kind of, different perspectives. A State prospective, pesticide registrant**

**prospective, a public interest group prospective and a grower prospective.**

**And then after that, if we've all stayed on schedule and I've earned my keep as a moderator, there will actually be time for you to ask questions of any of the presenters and to not only ask questions to clarify things you may not have understood in the presentation, but where you got advice or specific concerns that you think all of us should really be aware of. This will be an opportunity to share that with us.**

**I'm looking forward to it because as Jim said normally I think we like to do our business, as you can see, with registration review with quite a lot of public participation. I think with endangered species we've had a different approach, which, I think, in part flows from the litigation, which automatically puts you in a different mode. So, this will be a good opportunity, I think, to have some give and take around endangered species issues.**

**At the past meetings I have been doing this in**

**about 10 minutes. So, we've now blown it up to about 80 minutes.**

**We're going to try to give you a basic overview of the Endangered Species Act; a little prospective on the role of USDA in the whole Endangered Species/Pesticide arena; an understanding of what we in OPP thinks the Endangered Species Act means for us and how we do business; and then a session that will cover what we're calling ongoing issues and activities, and that will include a brief update on litigation, but we're not really trying to do a detailed litigation piece here.**

**Some things we're doing that we're styling as internal within OPP; a process enhancement; touch on the rule making that's underway under the Endangered Species Act; clarification of some of the just current technical and scientific approaches that EPA employs in doing Endangered Species assessments; some of our information needs; and then finally once we get all this together, how we're, sort of, envisioning this will flow out into the field and really work if you are an actual farmer in**

**the field trying to cope with EPA decisions that are in compliance with the Endangered Species Act.**

**And then the panel members have each been given -- the panel members all have two questions that we've asked them to, sort of, focus their remarks on, but also we're hoping that they'll bring, kind of, the unique prospective of that, sort of, larger constituency that they're from, so that you can not only have a government picture, but you can have an external to the government sense of things.**

**Just to, kind of, run through the government presenters, but I'll ask them each to, maybe, briefly reintroduce themselves so that you can actually put names to faces.**

**We'll start off with Joel Labissionniere representing National Marine Fisheries; and Rick Sayers from the Fish and Wildlife Service; Burleson Smith, who probably actually doesn't need this introduction again; Artie Williams from our Field and External Affairs Division in Pesticides; Mark Dyner (phonetic) from our**

**General Counsel's Office; Ed Odenkirchen from our Environmental Fate and Effects Division; Debbie Edwards from our Registration Division; and then when we get to the external panel folks I'll introduce them.**

**So, Joel, if I could turn things over to you.**

**MR. LABISSIONNIERE: Good morning. My name is Joel Labissionniere. I am an attorney with the National Oceanic and Atmospheric Administration. I'm in their Office of General Counsel.**

**As I understand, this is, sort of, the first time that you've had an intensive discussion with regard to the Endangered Species Act and Pesticides. And so this discussion here, including all of the presenters, is something of a basic primer to make sure that all of you are working from the same base level of information.**

**The Endangered Species Act has sometimes been characterized as the pit bull of Environmental Legislation. It is small, but it is powerful and it's got teeth. It is, without question, one of the most powerful pieces of Environmental Legislation that has been enacted**

**by Congress. It was enacted in 1973 in response to a belief by Congress that passed economic growth, inadequately tempered to take into consideration the concerns of species was resulting in an alarming rate of decline and extinction of species.**

**The act, as it was passed, was one of the first -- one of the first times it was looked at by the Supreme Court. The comment that they had was that in looking at it in its totality, it was clear to them that Congress intended to afford endangered species the, quote/unquote, highest of priorities.**

**It is administered by two Federal agencies; the Department of Commerce and the Department of Interior. The Department of Commerce, through the National Marine Fishery Service, which is a component of the National Oceanic and Atmospheric Administration, has jurisdiction over marine species and -- (inaudible) -- species that are listed, including salmonids.**

**The Department of Interior has management responsibility through the Fish and Wildlife Service over**

**terrestrial species.**

**The Endangered Species Act includes a variety of provisions that, for example, establish a process for identifying and listing endangered and threatened species commonly referred to as listed species, for establishing certain prohibitions relative to the taking of those listed species and also for identifying very limited exceptions to those sweeping prohibitions.**

**But our focus today, I think, is on one component of the Statute, Section VII of the Endangered Species Act. These are provisions in Section VII that apply to all Federal Agencies, although as we are going to find out that even though these requirements are directed towards Federal Agencies, they have significant ramifications to State and local government organizations and private entities as well.**

**Now, these obligations in Section 7 of the Endangered Species Act are both procedural and substantive. What I'm going to do is I'm going to spend just a couple of minutes talking about the substantive**

**component of these obligations and then my counterpart from Fish and Wildlife Service, Rick Sayers, is going to talk a little bit about the procedural side of these obligations.**

**The first obligation -- and there are two -- is found at Section 7(A)(1) of the Endangered Species Act, and it is actually an affirmative obligation that is imposed upon Federal Agencies. It calls essentially upon all Federal Agencies to use their authorities to conserve endangered species. And specifically, as the slide indicates, it directs all Federal Agencies to use their authorities to further the purposes of the Endangered Species Act by developing programs for the conservation of endangered and threatened species. And I think later on we're going to have a little bit of discussion in terms of how EPA is meeting their statutory obligations under this component, under Section 7(A)(1).**

**The bigger obligation is found at Section 7(A)(2), which is not an affirmative obligation. It is a prescriptive obligation. And it essentially requires**

**all Federal Agencies to ensure two things. First of all, that their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and also to ensure that their actions are not likely to destroy or adversely modify critical habitat.**

**Now what does that mean? What do we mean by actions here -- and the Statute talks about that and it talks -- it imposes this prescriptive obligation upon all Federal actions that are, quote/unquote, authorized, funded or carried out by a Federal Agency. Authorized, funded or carried out. That is exceedingly broad.**

**And, as we have found out in recent litigation involving a case entitled Washington Toxics Coalition versus EPA, a case that arose in Washington State, that these prescriptive obligations apply to EPA relative to the registration and re-registration of pesticides under FIFRA.**

**So, how do these Federal Agencies meet these obligations? Well, as I noted earlier, there is substantive and a procedural obligation associated with**

**Section 7.**

**Without fitting into what Rick is going to talk about, basically Federal Agencies are required to consult with one of the two Federal Agencies, depending upon the species that are involved, to ensure that their actions are either, (a) not likely to jeopardize the continued existence of endangered or threatened species, or (b) result in the destruction or adverse modification of critical habitat. This is known as the consultation process.**

**The Endangered Species Act establishes specific procedural requirements and time frames for conducting these consultations and both services have jointly promulgated regulations that also further establish the procedures associated with the consultation process. Next slide.**

**Now one of the issues that commonly arises with regard to these consultations is what happens to actions that are either contemplated or are ongoing relative to this duty to consult. Section 7 actually address that,**

**and Section 7(d) of the act provides that while in consultation, Federal Agencies shall not make any, quote/unquote, irreversible or irretrievable commitment of resources with respect to the action that has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative.**

**Essentially, the rationale behind that, I think, is twofold. First of all, it becomes, I think, a hollow exercise to engage in this consultation process if during the consultation process. Actions are ongoing that are ultimately going to undermine the obligation to avoid jeopardizing endangered or threatened species.**

**But, secondly, the Statute is structured in a way to allow the services of the National Marine Fisheries Service and the Fish and Wildlife Service, to help the Agency that is involved in undertaking the action to sculpt the action in ways that are consistent with the action so as to not only allow that action to go forward, but go forward in a way that is consistent with this larger substantive obligation that's imposed upon**

**Agencies.**

**So, with that, sort of, as a discussion as to the substantive obligation, I'm going to turn it over to my counterpart here who is going to talk a little bit more about the process associated with Section 7.**

**MR. SAYERS: Thanks, Joel. Again, my name is Rick Sayers. I'm with the Fish and Wildlife Service here in Arlington, Virginia. Our office is just a couple blocks away.**

**I am the Chief for the Branch of Consultation and Habitat Conservation Planning, so I'm probably one of the few people in the Fish and Wildlife Service who spends just about every waking moment of my day dealing with Section 7, consultation processes.**

**I want to make one minor correction to something Joel said in the very beginning. We, in Fish and Wildlife Service, have the responsibility for terrestrial species and fresh water species. So that -- not just the terrestrial species.**

**To continue on with the presentation at this**

**point, the consultation procedures Joel referred to, as established in joint regulations and if you're curious to find them they're at 50 CFR Part 402, and they're a fairly elaborate set of procedures that we have been using since 1986 when those regulations were established.**

**And as indicated on this first slide, there's no duty to consult if the action that an Agency is contemplating will have no effect to listed species or designated critical habitat. And that is a determination that the action agency is expected to make on their own and they need not receive any concurrence or they do not need to consult with the Fish and Wildlife Service or National Marine Fisheries Service in making that determination.**

**But there's a general expectation that they will, at the bare minimum, ask the expert agencies, the Wildlife Agencies to provide them with information about species that may be effected by the action and so we often are asked to provide something called the species list. And basically that is a list of those species or any designated critical habitat that we think might be**

**effected by the action and then we ask the action Agencies to take that list into consideration in making their determination.**

**So if the action agency determines that their proposed action will have no effect the consultation responsibility is concluded right then and there with documentation to the Agency files as to how they reached that conclusion.**

**If, on the other hand, the action agency makes a determination that the proposed action may effect listed species or designated critical habitat, they then do have a duty to continue on using the procedures established at Part 402 of 50 CFR.**

**Essentially within that there are two tracks that we can follow. One is commonly referred to as informal consultation and the other is referred to as formal consultation. Go to the next slide.**

**The first one, informal consultation, is essentially, first of all, you need to know it's an option process. The action agency and any applicant to the**

**action agency has no duty to engage in an informal process. But we often use that process to help determine whether formal consultation is required and in the informal process we have lots of discussion about are there modifications that could be made to the proposed action that would allow it to move ahead without having any adverse effects to listed species or designated critical habitat.**

**One of the biggest drawbacks from many people's prospective of the informal process is -- it's called informal for a reason. It doesn't have any specified timelines. It can go on for months, sometimes years if everyone is interested in continuing that process. There are those who think that that is a significant drawback. That, you know, gee, you get into an informal process and you never get out.**

**The simplest way to get out of it is to make a decision that we're not going to modify our action any further and if you think it has adverse effects, then we need to go ahead and transfer over to the formal process.**

**But -- hang on just a second. I really need to make one more point there.**

**But the last bullet on the slide then is probably the most important for everyone in the room to be aware of. If you engage in the informal process and the action agency and their applicant decide -- make a determination that the proposed action is not likely to adversely effect listed species or critical habitat, they need to request written concurrence from Fish and Wildlife or National Marine Fisheries Service with that determination.**

**If you don't get the written concurrence, you have not fulfilled your consultation responsibilities. If you do get a written concurrence letter you now have a complete administrative record that shows that you have engaged both the process and the substance that Joel spoke about earlier.**

**The term, not likely to adversely effect, is a term of art, but it has a fairly precise meaning and here it means that no individuals of listed species will be**

**harmed by the proposed action. I'll talk in a moment about why that's important, but you do need to recognize that's not a species level assessment. It really focuses down on how the proposed action is likely to effect individuals of the species.**

**Now, if you -- through the informal process or perhaps just -- you might decide you don't need the informal process. If you've decided that your action is likely to adversely effect listed species you can go directly into formal consultation. That's the stated requirements in the regulations.**

**When you enter into formal consultation the action agency is required to prepare documentation that describes how the action will effect listed species or designated critical habitat. That information is called an initiation package and it's handed over to the services for evaluation. Typically within 30 days we'll notify the action agency if we see any deficiencies in that initiation package and if there are none, then the formal consultation proceeds from that point on.**

**The next step in the process then is for the service --**

**(End tape one, side two.)**

**MR. SAYERS: -- produced by Fish and Wildlife or National Marine Fisheries Service, and within that we make a determination about those two key points that are referred to in Section 7(a)(2). You will get a very clear concise statement that says whether we think the action will or will not jeopardize the continued existence of any listed species and whether we think it will or will not destroy or adversely modify any designated critical habitat.**

**If you get a biological opinion that says not likely to jeopardize and not likely to adversely modify critical habitat, at that point you have, again, fulfilled your consultation responsibilities under Section 7 and there will be, perhaps, some other components of that that you'll want to be aware of. I'll highlight those in just a moment.**

**This formal consultation process is designed to**

**take 135 days from the time the consultation is initiated -- that is when the action agency transmits their package of information to the services -- and the time the services then return back with a biological opinion.**

**You can have -- the agencies can agree to extensions of that 135 day time period and if there are applicants to the process, any request for extensions beyond 60 days do require the approval of any applicant to the process.**

**I'm leapfrogging a little and I apologize for that, but if, in fact, the biological opinion comes back with a finding that it is likely to jeopardize the continued existence or it is likely to -- the proposal is likely to adversely modify critical habitat, there will be a section of that opinion called Reasonable and Prudent Alternatives. In that section the services will describe modifications that they think could be put in place that would allow the proposed action to go forward without jeopardizing the continued existence of listed species or adversely modify.**

**In the event that an action agency gets a jeopardy or an adverse modification opinion, they do have to notify the services -- I think it's within 60 days, but I'm not sure if that's a correct number. But they do have to notify the services of their final decision on how to go forward.**

**And their options at that point are they can go forward and simply implement the proposed action as they originally submitted it; they can agree to adopt one or more -- sometimes there are more than one reasonable and prudent alternatives. So they can agree to select one of the reasonable and prudent alternatives and move forward that way.**

**They can also agree that they need to make changes to the proposed action and they're going to do that, and typically if they take that course they actually restart the consultation process because they've changed the proposed action and we haven't necessarily evaluated that changed actionable effect species.**

**And then the last option available to them is to**

**seek exemption under Section 7(h) of the Endangered Species Act. I don't believe we have anything planned today to talk more about the exemption process, but if you have some questions at the end I can try to answer those as well.**

**Do I have one more slide? I think that's it actually. Oh, I'm sorry. Yeah, there is one more thing I'm supposed to mention.**

**In the biological opinion, assuming you get a non-jeopardy opinion, you will also have a component that's called incidental take statement. That statement provides an exemption from the taped prohibitions that are in Section 9 of the Endangered Species Act for wildlife species. You're not going to get an incidental take statement for plants. That's probably a more complicated subject that we need to get into right now.**

**But if you get a non-jeopardy opinion or if you get an opinion with RPA and you agree to implement one of the RPA, you can then have an incidental take exemption that conveys with the opinion.**

**MR. SMITH: I'm Burleson Smith and I'm a special assistant at USDA working on pest management policy. One of the reasons that you see me here at these meetings I because I serve as a liaison between the Department and EPA's Office of Pesticide Programs on behalf of production agriculture.**

**We are very interested in EPA's programs related to pesticides because of the necessity for the use of pesticides in efficient crop production.**

**Our interest is to see that the process -- or EPA's registration efforts are as efficient as they can be in order to allow for the availability of tools for production agriculture, and in doing so we look at a number of different areas. Obviously, not just in the endangered species area, but we comment and have the opportunity to provide insight on how these actions may impact agriculture as it is widely practiced throughout the country and there are many different variations in how practices may be handled.**

**So, we find that there's an opportunity to impact**

**the way that some of these programs will be structured in such a way that they are efficient by providing information to EPA and to help them understand where there may be unintended impacts from various regulatory decisions.**

**So, our overall interest is to see where any of these determinations can be refined so that they achieve the overall objective that EPA is endeavoring to do to protect the environment and human health, while at the same time providing the best possible set of conditions for production agriculture.**

**MS. WILLIAMS: Good morning. My name is Artie Williams and I'm the Chief of the Environmental Field Branch in the Office of Pesticide Programs. This branch is responsible for OPP's development and implementation of the program to comply with the Endangered Species Act.**

**I'm going to touch on what all of this means that you've just heard in terms of the Office of Pesticide Programs and registrations of pesticides, and then we're going to move into some ongoing issues and activities.**

**First, I want to make this point very, very strongly. That we must ensure that any pesticide is in compliance with the ESA and is not likely to jeopardize listed species or adversely modify critical habitat.**

**We have, however, determined that there would be a determination of no effect from pesticides that are solely indoor use pesticides. So, essentially what we're talking about here is assuring that any pesticide that has an outdoor use or a use where the product could get outdoors we have to make sure it complies with the ESA. That includes not only agriculture chemicals, but antimicrobials that are used in wells and any other kind of product. This doesn't just address agricultural products. It addresses lawn care products that homeowners might use as well.**

**Eco-risk assessments are, as I hope all of you know, an integral part of our registration decisions under FIFRA, and we're going to be talking a little bit more about how we do those assessments a little bit later.**

**But these assessments generally do not focus, as Rick had said, on individuals of a species. So, while the eco-risk assessment is integral to that and is kind of a base for us, it doesn't get us where we need to go to determine whether or not we're in compliance with the ESA. We use that as a screen and then we do a more specific assessment based on the products uses and the individual species that may be effected by that product.**

**I guess the bottom line is what is means for OPP is it's an awful lot of work. In order to get to a point where we can do that work more routinely there are a lot of ongoing things that we're involved in, and this is just a list of them. I'm not going to read them to you. You all can read.**

**But you can see there are a number of things ranging from things that we have virtually no control over; i.e., litigation, to implementation, which we hope to have a lot of control over and hope to be able to do fairly soon.**

**With that, Mark Dyner is going to summarize**

**what's going on in terms of litigation. We're going to, kind of, tag team here.**

**MR. DYNER: I'm Mark Dyner with the Office of General Counsel at EPA and I have been working on the Endangered Species litigation for the last three years. I think when I originally took the Endangered Species assignment it was, kind of, a backwater much like my work on FIFRA data compensation, but neither of them now are in that position.**

**Since late 2000 we've received seven notices of intent to cancel -- notice of intent to sue, rather -- you can tell where my mind set is. There we go. Under the Citizen supervision of the Endangered Species Act, and five of those cases have actually matured into Federal District Court litigation. I think there are only six listed there. There's an additional notice of intent to sue that's been out there for a couple of years and we're not listing it, but that is also from the Center for Biological Diversity.**

**I'm not going to walk through each of these cases**

**individually, but I want to highlight some of the key elements here. First, as far as where they're taking place. The initial focus of this litigation was -- in the first couple years, was exclusively in the Pacific states in the 9th Circuit. That's the cats case, the Washington Toxics case, and the California Red-Legged Frog case. I think that's probably a reflection of the fact that there are a lot of listed species in that area, a lot of environmental groups in that area, and very favorable might circuit precedent for plaintiffs.**

**But in the last year or two we are seeing litigation and notices of intent to sue that cover numerous regions of the country. The NRDC case regarding obtrusion addresses species in the Chesapeake Bay region, the Midwest and parts of the south as well. The Barton Springs case is central Texas. The Defenders of Wildlife case is in part of Florida.**

**The thrust of most of these suits is Section 7(a)(2), which Joel and Rick discussed earlier. In general, the plaintiffs in these cases are alleging that**

**EPA has failed to satisfy its obligation to consult with either the Fish and Wildlife Service or the National Marine Fisheries Service regarding the effects of currently registered pesticides to numerous plant, land, animal and aquatic species.**

**In many of these cases, the plants are also asking that the Court enjoin the use of these pesticides within species' habitat pending EPA's completion of any required consultation.**

**EPA ha reached a settlement in the CATS case as a consent decree, which is a Court ordered settlement, to initiate consultation on 18 pesticides as it relates to 33 different plant and fish species, I believe, over a two year period. But the other cases remain active.**

**At this point, only one of these cases has resulted in a substantive Court ruling. That's the Washington Toxics' case. In that case, in July of last year the Court ordered EPA to make effects determinations and then consult, as required, on the effects of 55 -- pesticides containing 55 different active ingredients as**

**it relates to all the listed specific salmonids. Then that's 26 different runs of salmon and steeled in the Pacific states and we're to do that over a two-and-a-half year period.**

**This last August the Court issued a preliminary order informing the parties that the Court will be imposing use restrictions around salmon stream pending EPA's compliance with that July 2002 Order. We, at this point, expect the Court's final Order putting the injunction in place at any time and we believe the effective date is likely to be the end of November. The Court ordered the parties to go back and actually negotiate the terms of his preliminary order and the parties -- one of the things the parties were able to agree on was a date of November 30th.**

**What this means is, as I said, there will be Court imposed restrictions for certain pesticides around salmon streams in the three Pacific states next use season. Once the actual order comes down I think we'll be in a better position to clarify what the scope of that**

**Order is and the circumstances under which it can be lifted or modified. And, as I said, we expect it at any time. My guess would be in the next couple weeks.**

**While I'm not going to prognosticate what the results of the other litigation will be, my sense is that plaintiffs are likely going to take a similar tack to the Washington Toxics case, and at the first phase where we address whether or not EPA has an obligation to consult under the Act, and then move on to whether or not there should be inner measures in place, injunction in place while EPA complies with that Order.**

**MS. WILLIAMS: Because we don't ultimately want our schedules being set by Courts and being under Court purview and because we want to be in compliance with the Endangered Species Act, we're looking at two major areas for process changes inside the Office of Pesticide Programs.**

**Currently the way that we work is the Environmental Fate and Effects Division does their eco-risk assessment and we use that in my group as a**

**screening level assessment, and we go on from there to do the species specific work.**

**One of the things we're looking at is whether that is an appropriate split, whether the baton needs to change once the screening level assessment is done, or whether there is more that could be done in that first step, thus moving process forward a little quicker.**

**The other thing that we're looking at doing is integrating the Endangered Species assessment into our standard processes for registration and re-registration. Currently, again, during those processes a determination is made as to whether a numeric trigger has been hit for fish or birds or amphibians or plants, and if that trigger has been hit that signals us to do a specific assessment for those kinds of species.**

**The process of registration and re-registration continues on, however, while over on the sideline we're doing the endangered species assessment. What this results in a lot of times is a decision being made on the registration action or re-registration action prior to a**

**determination as to whether or not there is an issue with listed species.**

**Our goal is to integrate that endangered species process into these others so that when a decision comes out at the end a registration decision or re-registration decision, a new use for an existing registration, we've done the endangered species assessment, we either have determined that there is no effect, we've taken steps to mitigate any effect or we're in consultation with the services at that point.**

**It's kind of like -- I guess Anne once skinned all of this to the new FQPA and I feel very empathetic with and sympathetic to those people who had to implement FQPA because you were implementing it while you were developing it and this is kind of where we are with this.**

**But this is going to take a lot of thinking and a lot of creativity so we can do this within these processes and this is key without slowing those processes down because we want to continue the pace of the registration and re-registration actions.**

**Another thing we're doing -- Mark.**

**Mr. DYNER: Yeah. One of the things that the service consultation regs allow is for the services and action agencies to develop counterpart regulations to more finely tune the consultation process for a specific agency or specific agency program. It was actually in January of this year that we issued an advanced notice of proposed rule making to do just that for the pesticide program.**

**As we stated in that advanced notice of proposed rule making, ANPR, EPA and the services in USDA shared the belief that we can find ways to improve the effectiveness and efficiency of the Section 7 consultation process. ESA, as most folks know, has dozens of biologists working full-time doing ecological risk assessment for pesticides, and given the size and level of expertise of that staff, we think there is a real opportunity for the government to achieve some economy while meeting it's ESA obligations under Section 7. So, proposing and completing work on this rule**

**remains a high priority for the services in ESA and USDA.**

**To that end the ANPR put forward three possible options for a counterpart consultation regulation and I'll go over those briefly.**

**One option would be that it would allow EPA and the services to make better use of what are known as programmatic consultations that could address numerous registration and re-registration actions simultaneously. As most folks know, we have something like 19,000 active registrations and, you know, it's our sense that there are certain classes of pesticides, certain similarities that may allow us to make certain -- to make broader -- to consult in a broader way to address many of them at the same time.**

**A second option would allow EPA to make certain low risk findings and one of the points that Rick and Joel were alluding to in their discussion was the not likely to adversely effect finding and that that could currently conclude consultation with the concurrence of the service.**

**I think one of the things the counterpart -- or the ANPR looked at was whether in those circumstances where EPA is able to make that finding, whether there would, in fact, be a need for further consultation with the services.**

**The third option that was presented in the ANPR was an option that would result in the services providing greater deference in the consultation process to EPA's effects determinations.**

**In addition to those options, the ANPR also took comment on a number of ways that the existing ESA and FIFRA processes could be modified to increase effectiveness, efficiency and flexibility. One of those areas was finding ways to create an efficient and transparent public process so that as we make determinations and consult, we can provide a meaningful opportunity for registrants, growers and the public to participate in the process while meeting the statutory obligations and timetables set forth in the ESA, and we are committed to doing that.**

**Currently EPA and the services are in the process of reviewing and considering the many hundreds of comments that we received on ANPR. Thank you to those of you in the audience who submitted comments. And we are working to develop a proposal. At this point, I can't provide a precise time frame for when that proposal is likely to issue in the Federal register, but as I said it remains a high priority among, again, EPA and the services and the USDA.**

**MR. ODENKIRCHEN: Good morning. I'm Ed Odenkirchen. I'm a senior biologist with the Environmental Fate and Effects Division within the Office of Pesticide Programs and I'm here to talk to you this morning a little about the screening process that we conduct for ecological risk assessment.**

**And the first picture that we have up on the board, if you were to show a map of the United States to an ecological risk assessor within our division, this is pretty much the way they think about the United States day in and day out. Where are pesticides are used; which**

**crops they're used on; how often they're used, et cetera. And that is our screening level process. It may involve the use of pesticides across multiple crops, across tens of millions of acres of the United States.**

**As we move more towards individual species within the ecological risk assessment for endangered species, the species specific universe may extend down to one watershed, a small reach within a stream, a few vital pools, a mountain top. And that is a challenge for our division is how do we conduct our screening level risk assessments to adequately incorporate that and not hinder our process of making timely regulatory decisions on pesticide use. Next slide.**

**Basically, our screening level process is conducted in the same manner as we conduct for non-endangered, non-target species. We have a suite of environmental fate data and a suite of toxicity data for non-target species, and we use that information in a set of models to make inferences with regards to risk.**

**However, the difference between endangered**

**species and non-endangered species in a screening level process lies in the evaluation criteria. When we look at that data in toto and we take an integrated approach for looking at fate and looking at effects, we have a tendency to be more conservative with regards to endangered species than non-endangered species in making decisions of potential for effects.**

**I really need to stress to all of you that our screening level assessment is not intended to be specific to any individual species. It is a very useful tool for making decisions when we do not have concerns for effect and proceeding forward in a timely fashion. It is also useful for us to work towards refining our assessments at a species specific level.**

**Looking at exposure for endangered species at the screening level, it is not tied to an individual species location. We take a conservative approach that the endangered species is present on or near the site of pesticide application. For aquatic exposures, we base our exposure analysis on a series of surface water models**

**and drift models, and it may also make use of existing monitoring data and we use our existing environmental fate data and use patterns and selections of sites to create upper bound conditions of exposure.**

**For terrestrial exposures we base our exposures primarily on a series of dietary analyses that look at pesticide application and the means of application to make inferences on how much residue there are in individual dietary components. Next slide.**

**On the screening level effects for effects toxicity, they're conducted like non-endangered species. We have a suite of studies, which are prescribed in 40 CFR Section 158, that allows us to make determinations on acute and long term effects of pesticides to survival and reproduction and some behavioral characteristics.**

**We usually do not have data for toxicity for endangered species per se. We use a suite of surrogate species; two fish species, two bird species, some invertebrates and some assorted plants. And we use those toxin endpoints to select from the most sensitive species**

**tested within some broad taxonomic groups. Our assessments at the screening level are conducted for birds, mammals, fish, both freshwater and estuary, aquatic invertebrates, both freshwater and estuary, and plants, which includes vascular and nonvascular aquatic plants and terrestrial plants, including monocots and dacoities.**

**The typical endpoints for all these studies and what is finally ascribed to each surrogate species and then as an extension to endangered species, relate to acute mortality, reproduction and growth effects primarily. Next slide.**

**Well, how do we take that exposure information and that effects information and put it together to make -- come up with a risk assessment? We use what's called the Risk Quotient method. It's a fairly standardized method for a variety of screening purposes across the agency and, indeed, across other agencies, and essentially it's taking and comparing an estimate of environmental exposure and dividing it by an effects**

**estimate to come up with what we call a quotient. So, ratio or how high or how low exposure is in comparison to the toxicity endpoint.**

**And these risk quotients are compared to what we term levels of concern to determine if there's a potential concern for effects on an endangered species. Next slide.**

**The strengths of our screen. Number one is not even on here. It is that the screen allows us to make some rapid decisions in order to go quickly to regulation on pesticides, which do not trigger high degrees of concern. The screen uses the same conservative assumptions as assessments for non-endangered species. So, the screen is uniform in its application and it is consistent in its interpretation. The screen can indicate the potential for adverse effects and endangered species if exposure occurs.**

**Now, that's an important concept. If you go back to our original slides, one of the things that we have indicated was that the screen is not species specific.**

**What the screen can tell us is if exposure was actually to occur for an individual species at the level for which we have modeled, we may have a concern for an effect.**

**However, we would have to go to an individual species if that screen has failed and evaluate temporary and geographically where a species occurs in relation to how the pesticide is used, where and when it is used to determine if exposure actually does occur; and it allows us to focus that further effort where it is needed so we have hundreds of decisions that are made on thousands of compounds and use sites annually and it allows us to focus our efforts for looking at species specific evaluations for only those for which our screen is not past.**

**Thank you.**

**MS. WILLIAMS: If, in that assessment, it's determined that there is a potential for a species to be exposed at levels of concern, as Ed mention, we begin a species specific assessment.**

**Basically what this assessment is that the**

**refinement of the exposure component of the work that Ed's group did in the screening level assessment, he mentioned that their assessment is not specific to a particular species and there are many things about a particular species that would either increase or reduce the potential exposure. So that is what our group looks at.**

**For the initial determination, if the assessment from Ed's group comes to us and it says there is a concern for birds. The first thing we do is we identify all of the listed birds that may be of concern, and what counties those species are found in. We also determine whether the labeled uses are likely to occur in each of those counties. So, it's a broad county level screening to determine whether there is proximity between any of the individual species we're now looking at and areas where that pesticide might be used.**

**The second thing that we do is we look at the models that we used in the screening level assessment and, as Ed mentioned, they use models to estimate exposure, be it in water or on land environments. The**

**models that are used there are the models that are most appropriate to get a national picture of what this might be.**

**When we're looking at an endangered species, however, we may want to refine that, and I'll give you an example. If there's a scenario for looking at the exposure from the use of a pesticide on cotton in Mississippi, but what we're concerned about is cotton that's now newly being grown in Minnesota, the environmental conditions in Minnesota are probably quite different from those in Mississippi. So, the model that was used as a national model may not be appropriate for the geographic location we're interested in.**

**If that's the case, we work with the Environmental Fate and Effects Division to run some more appropriate models for the specific scenario that we're concerned about.**

**We then determine whether the specific use instructions on the label would preclude exposure at levels of concern, and by that I mean, if there is a**

**species that we're concerned about that eats only flying insects and this -- the use is to soil incorporate and we can determine that these insects are not likely to have pesticide on them we could determine that there would likely not be any exposure.**

**And then we look at the geography and the biology involved in this. The first thing we do is determine whether the geography of the area we're concerned about limits exposure in any way. There are some species, for example, that on our first screen when we're doing the County level assessment, may appear in a particular county. When you look closer at the geography of the county and the requirements of that species, you may determine that there's a mountain in the middle of the county and the species is on one side and cannot cross over the mountain, and the agricultural use or the homeowner use of the pesticide is on the other side of the mountain, thus precluding exposure.**

**We also look at whether the species' biology or the habits of the species have any potential to change**

**exposure. If there is a species that lives only at 6,500 feet elevation and above and everything in that particular county at 6,500 feet elevation and above is solid rock, it's not likely you're going to be spraying cotton with a pesticide in the rock.**

**So, we look at its habits, we determine what it eats, if there is a potential for dietary exposure, whether it eats in short grass environments or not. So, basically what we do is each step that we take we're refining the exposure side of the equation specific to that particular species in the taxonomic group that the screening level assessment indicated there may be a problem with.**

**The end result of this refinement is that we need to make a specific determination. The choices we have at this point are that there is no effect on the species, and in that case, as was mentioned earlier by the services, no consultation is required. We make a no effect finding when there is no exposure of concern. If those refinements get us to a point where we determine**

**that this is no overlap in the pesticide use area and species, we could make a no effect finding.**

**If there is some exposure, we would be making a may effect finding, in which case one or both of the consultation processes that the services look up earlier, would have to be employed.**

**For may effect we have two choices: not likely to adversely effect or likely to adversely effect. If we determine that it's not likely, we can proceed into informal consultation if we choose to. We would make a not likely to adversely effect finding when there may be exposure and there may be exposure at levels of concern. But there are some mitigating factors, which I'll speak to in just a moment.**

**Likely to adversely effect would be the highest level of concern we would articulate at this point and that would be where there is exposure at levels of concern and there are no mitigating factors or factors that can characterize that better.**

**Let me mention that for a second. Once we do**

**this assessment and we determine whether it's a not effect, a may effect, likely, not likely, we then look at some other things that we don't use to make the determination, but we use to characterize the determination, if you will. We employ incident data. We have an incident data system, not only under Section 6(a)(2) of our Statute, but we also have one that's run by the Environmental Fate and Effects Division and is populated with voluntarily submitted data from across the country.**

**So, we would look at incident data. See if there were any incidents that made us more concerned about this exposure or whether there, perhaps, were no incidents, which might mean that we were less concerned.**

**We also can use sales and use information to characterize the exposure. For example, if the screening level assessment was done using labeled application rates, maximum number of applications, smallest interval between applications, if we have sales and use information that shows while all of that is true this**

**particular pesticide is rarely used in that county, they prefer this other pesticide. While we can't base a determination on that, we can use that to characterize the degree of concern we have about that species in that situation. Same with local use practices and same with monitored levels in the environment.**

**I just want to say one short thing about monitored levels in the environment because a lot of times people go, well, wow. If you're really finding out what's out there, isn't that the best source of information? If it's there, it's there. If it's not, it's not.**

**But the fact of the matter is unless a monitoring program is designed to give you specific information, it's really difficult to rely on it to make a particular decision. So, we use that to characterize the risk rather than to make the decision as to whether there is risk or not.**

**MS. EDWARDS: My name is Debbie Edwards. I'm the Director of the Registration Division in the Pesticide**

**Program. This next section has to do with information that could be helpful to the Agency as we make these assessments -- risk assessments and also the risk mitigation decisions.**

**One of the things that we're working on now is we have a committee working toward the development of a PR notice that we will issue that could provide guidance to the regulated community on information and data that they could provide to us that would inform our assessments in the endangered species area. Of course, as all PR notices, this would go out initially for public comment before it went to a final stage.**

**But just to summarize some of our ideas thus far in this area, I don't think there are any surprises here. These are things that regulated communities have done for years with respect to other types of assessments and probably to some extent in this area as well.**

**First of all, our recommendation is that you go ahead and do a baseline screening level risk assessment based on the information that you're submitting in your**

**registration package. I think the methodology to do that is pretty clear to everyone, and even possibly take that beyond the tier one assessment and go toward -- or the screening assessment and do some refinements if you think those are appropriate.**

**Obviously, if your LOC is exceeded for a class of non-target organisms, particularly endangered species, we're going to need to go further so you could move forward yourself in that area as well.**

**The next piece of information as already described is determining whether or not you have an overlapping of listed species ranges within the potential use areas and within the timing that anticipated for that pesticide application.**

**There are a number of ways that you can look toward getting that type of information to assist us. One is that when the services list a species, they go through a public process. It involves FR notices and these FR notices provide information on the range and habitat of the listed species, as well as information on**

**their behavior, migration patterns, mating, nesting and so forth.**

**A second option would be to seek information from private sources or semi-private sources. One example is the Natureserve system, I think many of you are familiar with. Other might be university sources, State governments and so forth.**

**And also you could just cite the data from the FIFRA Endangered Species Task Force. Many of the companies that are represented in this room are members of that task force and they are -- have actually purchased the information from Natureserve and have been developing an information management system that will allow the Agency, as well as themselves, to do more detailed assessments in this area.**

**And finally, will be beneficial, we believe, to go ahead and make some proposals around effective risk mitigation. Obviously these are just some examples of things you might consider, but obviously the timing of application can be important. You can reduce your**

**application rates to the extent that ethicacy allows to reduce your risk quotients. Obviously buffer zones can be effective to protect rivers and streams and aquatic organisms -- other organisms occasionally.**

**And finally you can off-label -- you can make your own proposals regarding off-labeling of specific geographic areas.**

**MS. WILLIAMS: And I guess all of this leads to implementation. Actually, putting the program on the ground, out in the field.**

**In December of 2000, the Office of Pesticide Programs issued a Federal Register notice and it was a proposal for how we would implement this program once we -- once it becomes a routine part of our business. And the final FR notice is under development currently. I'm hesitant to predict when that might be out the door, but I would predict that it's not going to be a long, long time. It's pretty well under development right now.**

**In terms of the proposal that we requested comment on, there were far more details than this, but**

**there were three specific points that I think are probably the big points. Products requiring use modifications would have to carry a label statement that directed the pesticide user to obtain another piece of paper that told them the specific limitations on use for the county in which they're using it.**

**We propose that this specific piece of paper, or this county level bulletin, would have a map that would depict the geographic area within a county where pesticide use needed to be limited. It would indicate those particular pesticides and it would articulate what use limitations had to be employed in those areas.**

**The third, kind of, major thing in that notice was that by putting label statements on that refer people to this other information that they have to follow, we basically would be making those limitations enforceable under FIFRA. They would, basically, be an extension of the label, label use requirements, and would be enforceable under FIFRA.**

**There are some overall implications for**

**pesticide decisions because of our need to comply with the Endangered Species Act and our desire to do so. First, incorporating refinements in the registration and re-registration decisions. I mentioned earlier that we are looking at internal processes to do this and our goal is to do it without any delay in the current time line for issuing registrations or re-registration decisions.**

**Secondly, the decisions -- those decisions will need to either, in the future, address endangered species issues in full or get us to a point where we know we have to be in consultation and we're actually actively in consultation with the services.**

**And then the third is that in the future there may be products that would be required to carry such a label statement as I mentioned in the implementation end of this.**

**MS. LINDSAY: That's the conclusion of the government portion of the presentation. What we would like to do now -- you see our additional panel members listed up there, Bridget Moran from Washington State**

**Department of Agriculture; and -- I would just note -- we asked Bridget actually to make, sort of, a special trip to do this and we're glad she was able to accommodate it because Washington State is doing some very interesting things at the State level with regard to endangered species. And while we don't think that necessarily all States may need to do this level of effort or have the resources, I find that we're learning from what Washington State is doing and we thought that, perhaps, many of the rest of you could take this as a learning opportunity.**

**Beth Carroll from Syngenta -- and I will say again, Syngenta is doing some interesting things. Beth is actually going to go last on the panel for, what I will call, technology reasons. So, even though she is listed second, she is asked to be put at the back end.**

**Patti Bright, American Bird Conservancy, and Rebecca Freeman, American Farm Bureau Federation.**

**So, Bridget, if I can ask you to come to the table.**

**And by the way just -- I should have said the**

**two questions the panel were given, which seem to have disappeared from the screen, but I think are in your -- are the questions -- but they're in your handout. Were, sort of, how can EPA be more effectively communicating and interacting with all of our stakeholders given the variety and pace of some things that are going on. And then the second question was, sort of, in the longer term how can all of you and each of the, sort of, constituencies that these four panel members represent actually help to make the program more successful.**

**MS. MORAN: Thank you, Anne. Thank you all for the opportunity to come here and talk about what the activities are in the State of Washington. As the General Counsel referred to earlier, we are the State where the Washington Toxic Coalition law suit**

**(End tape two, side one.)**

**MS. MORAN: -- crops growing over 250, which have very minor pesticide uses in many cases, which are frequently the ones that are targeted for cancellation at times by companies as you all know because of the**

**profits.**

**With respect to the two questions -- I'll get to it in just a moment. I want to just take a quick step back.**

**The Washington State Department of Agriculture essentially did an internal risk assessment about three years ago and looked at the potential for litigation under the ESA as a result of the salmon listings. We began an interagency task force looking at options of consulting at the State or regional level in light of the fact that EPA was working toward implementing its program. But as I said, we had great concern that actions and litigation were going to come about sooner than that may happen. At about six months into our interagency task force, the toxics coalition filed its notice of intent to sue and we've been down that path ever since.**

**With respect to the two questions, the fast pace of decision making, how can we keep -- how can EPA keep the public informed and involved. The State Department**

**of Agriculture would promote the idea that to distribute information through clearly previously established channels, EPA has a very good information exchange with the State lead agencies, of which the Department of Agriculture is one of. We have very good communication with Artie and her shop in the Endangered Species Protection Program.**

**We would like to see, which we have -- as things develop very rapidly, sometimes it's difficult to do -- periodic phone briefings and, perhaps, even regional type coordinators in areas where we have very quickly moving issues.**

**One of the things that our Department of Agriculture, Endangered Species Program does is we have a website where we post all the current legal activities that are going on and we get an enormous amount of contacts from people who just want to get the basic information for themselves to see what are in these Court documents and read them for themselves, rather than reading the public perception of it or interpretation of**

**it through the media.**

**So that's one thing that I think the State lead agencies probably could provide an opportunity to provide information to the public because people come to us already for information relative to ESA, or any type of pesticide action.**

**With that, also, I would say probably the regions -- I know Region 10, in our area, gets questions all the time on what's going on with ESA and pesticides. And so using the regions, again, as a previously established mechanism is good.**

**And then finally, EPA's web site, which I find they use effectively already to provide information out to people. I use it all the time and I'm always pointing people in that direction of all the effects determinations that are out there, the time lines that are coming up and ways to provide information are clearly outlined there.**

**The second question here is of greater value to the Department of Agriculture of how our type of**

**organization can assist in the successful implementation of this program and what we can bring to the table. What the Washington State Department of Agriculture has done is to essentially try to assess mechanisms to refine the exposure assessment as already referred to. We go through -- we see the screening level assessments that come out of EFED. We also think that they are very well done.**

**One concern that we have, which I know is clearly one that Artie's group has, is how to refine the assessment down to the local level to accurately characterize what is going on on the ground in that area. We certainly feel, as being 3,000 miles away, we have an opportunity to know the geography, the spacial and temporal distribution of both the species that are present, as well as the commodities that are grown, the diversity of pesticides used on those, and how to -- our goal is to accurately characterize that and provide that information to the EPA so that when they sit down and do their refinement of assessment they have the best**

**information possible.**

**The way that we have gone about doing that is to develop a program that has -- we've developed what's referred to as the GEO-Spacial database where we have information that geographically specific tied to a data system. In that what we do is we have gone out and mapped the agricultural production areas of our state at the section levels.**

**As I mentioned earlier, we have 250 minor crops. We have an east and western side of our State, which are vastly different. I think everybody thinks of Washington State as Seattle and wet. Well, that's really a very small piece of our State. The whole eastern side of the State actually looks like a desert and that's where a majority of our agricultural production areas are. And so for us to be able to, again, accurately characterize the diversity of crops that are grown in the different regions is very important. So we have gone and mapped the agricultural production areas, which are in, as a layer, in our Geo-Spacial database.**

**The other thing that we are currently working on is a pesticide use schedule for those commodities. Unlike California, we don't have a mandatory pesticide use reporting system. And so for us to accurately characterize to EPA what is going on within each watershed, it's critical for us to identify where, when, and how pesticides are applied. We have many different irrigation type practices. How those effect pesticide transport. And so we document all of that into this Geo-Spacial database that we are developing.**

**The other piece that we are doing is a surface/water monitoring program. As Artie mentioned, one of the problems, if you will, with historical pesticide monitoring data is that it's not clear how that is tied to the application of pesticides on the ground.**

**We, as the State lead agency for regulating pesticides in the State and developing these use schedules with the growers -- again, all of these schedules are done with the growers. We sit down commodity by commodity and work with our grower**

**organizations, our commodity commissions, field consultants, basically anybody we can get to return our phone calls and sit down with us, which actually has been very good because we've got a lot of commodities that are concerned and have interest.**

**And so, we are out monitoring when we know the applications are current. So, we have a surface/water monitoring program in our most heavily agricultural base and that's gone with weekly surface water samples through the majority of the application season and then throughout the season as well on an every other week schedule.**

**So, to us, having this information in addition to the salmon habitat information that we brought in from our State Fish and Wildlife Agency in this Geo-Spacial database, we can start to develop a more refined assessment as to what's going on. We provide that to EPA for them to use in their effects determination.**

**Now, I think one of the questions I get asked all the time is wow, that sounds great. What does it**

**cost, which in times of -- in Washington State we're having a severe budget crisis right now. Not as bad as California, but bad for us. Ever since 9/11, Boeing has been on the decline, which is our major industry in the State next to agriculture and so we have budget shortfalls just like everybody else does. But we felt that the loss of agricultural pesticides is of a greater economic impact to our growers than the value of not having our program.**

**And so, it's a situation where yes, it does cost us money to run the program, to map this, to develop the Geo-Spacial database. Now that that is developed and being populated, it's cheaper to maintain than to actually develop from the start. But it has been a priority for us at the State level, such that we have spent the money and it appears to be paying off.**

**The ability for us to provide much more refined information to EPA and then work with them on development and implementation is going to provide our growers, we believe, with much less restrictions than -- much more**

**refined restrictions, if you will, rather than the broad based buffers that we're seeing in the Washington Toxic Coalition law suit.**

**We're looking for a much more surgical type approach than these kind of one-size fits all. While we certainly understand -- we take great respect with the notion that we must protect endangered species. We don't take that lightly, but we want to maintain a viable agricultural community as well.**

**And so our goal is to maintain pesticide use by, but keep the pesticides out of water. And by our multi-dimensional type approach by identifying where they're used and how and monitoring the water, we feel that we can work with our growers to modify uses if need be, but to keep the tools available.**

**MS. LINDSAY: Patti, I think you're next.**

**MS. BRIGHT: Thank you. I think from the environmental nonprofit public advocacy side, whatever you want to term us as, I think for us the real key issue is that it is extremely important for EPA to identify**

**non-industry stakeholders and to get those stakeholders involved in the process as early as possible.**

**When you look at the current processes that are in place, I think there is a fairly well defined network of industry stakeholders for a lot of these issues. For example, if a pesticide issue comes up EPA contacts the registrant, be that Bayer, Syngenta, whoever. They generally know exactly who to call, who is going to be concerned about those issues, the grower groups -- you know, State Agricultural agencies, whoever. So it's very easy for the word to get out to those organizations. It's very easy for them to get involved. EPA has worked with them a lot, so they know who those stakeholders are.**

**There's a gap there on the other side. We don't have that well defined network. It's not in place. EPA doesn't always know who to identify as the nonprofit stakeholders. I think that is something that really -- that's a real key issue that needs to be addressed, and I think that the nonprofits can certainly help you to do that and we're very interested in helping you to do that.**

**I also think -- and this is a little bit of an aside, but EPA works very closely with USDA. We've got the Office of Pest Management. Whenever there's an issue going on the Office of Pest Management is involved and as such the State Agricultural Agencies are involved.**

**I think we also need to have that same type of connection and network from the Wildlife and DNR side of things. So, there is no similar office to the Office of Pest Management for Fish and Wildlife Service. There is a contaminants division. They do have some people who work on pesticide, but there's no full time staff that do that as opposed to the Office of Pest Management who do have full time staff who do nothing, but work on these issues.**

**I think we need to identify and find -- you know, find a way to get Fish and Wildlife Service more involved and also to get the State level folks more involved in these issues.**

**In terms of developing that stakeholder network, as some of you who have worked with me and worked with**

**other people around the table know, in the past year we have developed or come together as what's called a National Pesticide Coalition, and right now that Pesticide Coalition has 20 national groups. Some of them were listed up there as Plaintiffs in lawsuits.**

**But what we are trying to do by developing this National Pesticide Coalition is to come together as a united voice. And what I often hear when I come to these meetings or when I talk to registrants on individual issues is that registrants and EPA -- well, particularly registrants, I think, feel many times that they are shooting a moving target.**

**So, EPA identifies what they think are the key issues, the registrants go out and answer those questions, and then the next thing you know the American Bird Conservancy comes in, you know, 75 percent of the way through the process and says wow, wait a minute, you're not answering the right questions. And then after I come in maybe NRDC steps in and says, well, wait a minute. We have questions about children's health.**

**And so I can imagine that that's extremely frustrating for registrants' side of the process. It's extremely frustrating from our side of the process.**

**What we would like to do through the coalition is to try and get together so when we identify issues we sit down early as a group and try and look at wildlife issues, general environmental issues, children's health issues, migrant health worker issues, and come together with the united voice to say here's what we think the key questions are and here's what we would like to see answered.**

**So I think -- you know, in going back to your slide about the lawsuits, I think everyone would agree that those are extremely resource intensive or time intensive. Nobody particularly likes being involved in those. And I've said this before, so bear with me for those of you who have heard me say this, but from the nonprofit side often times we throw up a lawsuit because we feel like it's our last opportunity to somehow say no.**

**The process is moving along. Registrants see it**

**as already, you know, 75 to 80 percent of the way done when we step in and go, wow, wait a minute. You haven't done what we think you need to do and no one is listening to us.**

**So, I think really one of the keys here is to -- how do we prevent those bumps in the road as we get down the process and the key really is identifying all the stakeholders early and getting all of those stakeholders involved early so that we can identify the key questions that need to be answered up front, and get people -- well, we'll probably never come to complete consensus on anything, but at least try to come to an idea of what we need to answer before we move forward. And I think that would really resolve a lot of the issues that we're seeing with these lawsuits.**

**As I mentioned, we have this National Pesticide Coalition. Right now we have 20 groups that are representing different interests. We hope to expand that out. We hope to, at some point, have a couple hundred groups involved in this, and we hope that in doing that**

**we will be able to develop, kind of, a rolodex for EPA to use as a stakeholder rolodex -- a non-industry stakeholder rolodex. As I said, we are very, very interested in working with EPA in helping you guys to identify who those stakeholders should be.**

**In terms of interacting with stakeholders, another way that EPA might do that is to try and get the word out to some of the listserves or other methods that environmental groups are tied into. Certainly a lot of the industry folks are tied into some of the journals that are out there or have -- as I said, have a pretty well defined network. So, if the word gets out to the registrants they pretty much know who they need to filter that out to.**

**That's not really happening right now with the environmental groups. We do -- the coalition does have a listserves so certainly, you know, contacting us, we're going to filter it out to our members. But we think it's important that it gets out to a broader audience and, you know, I can certainly be happy to talk to you separately**

about a couple of suggestions I have for how you might do that.

Going back to the discussion that we had earlier this morning regarding the pesticide registration issues. We talked about, during some of those recommendations, how important it is to have a very comprehensive E-docket so that stakeholders know where to go to get the information so that they know what's available, and they can, kind of, follow the history of what's happening. And I think that really applies here too. And when I talk about a comprehensive E-docket in this situation I mean also making sure that information about where you think the species are, what the habitats are using are -- you know, having all that information out there so that both sides can look at it early and address whether there are issues early on.

Also, I would encourage EPA when you hold a stakeholder meeting -- when I've been involved in some stakeholder meetings oftentimes there are a great many more registrants than there are -- excuse me. Not

**registrants. A great more industry folks than there are non-industry folks.**

**Again, I think it's really important that all the participants are there. I think that when you're holding stakeholder meetings, really making those as open as possible would really benefit you because it's great if we meet with EPA, but it's hard for us to address the issues from the other side if we don't know what those issues are.**

**I know that there -- you know, there's certainly a lot of mistrust when people sit down at the table like that, but the only way we're going to get these issues worked out is to sit down and try and understand -- you know, I'm not anti-pesticide and neither are the rest of the groups in our coalition, but what we are is promoting just use of pesticides.**

**And so sitting down with USDA, sitting down with the registrants, sitting down with other industry folks allows us to understand the issues, and that's really what needs to be done because there are many times when I do**

**sit down and talk to someone from industry and I get a whole -- you know, just a completely different viewpoint on something. And so I think it's really important that we encourage that.**

**And I think that's it. Thank you.**

**MS. FREEMAN: Thank you all for having me and listening to the grower prospective. I'm privileged to represent both my organization, which is the Farm Bureau, and all my State members, as well as, hopefully, the other commodity groups that I share membership with and who have members that are separate from my own.**

**In order to address the first question, which is more of a short term communication question, especially in response to some of the litigation and some of the Court imposed requirements that my farmers are going to have to put on the ground and live with and adjust to, at least in the short term until a more formalized acceptable process, hopefully, comes out through counterpart regulations.**

**I have four points I'd like to make really**

**quickly on that. First of all, we do need to go forth and improve the process through the counterpart regulations in whatever form they come out. Certainly we have ideas on how we would like to see them come out, as do others. But, obviously, what's going on as far as consultation or lack thereof is not acceptable to the Courts and it needs to be resolved -- it needs to be resolved once and for all and conclusively so that the Agency can go forth with the busy of registering pesticides and the services can go forth with the process of protecting endangered species.**

**Secondly, if the Agency and the services can engage existing channels, from looking -- certainly the west coast and the Pacific Northwest are far ahead of probably the rest of the country in setting up the appropriate State level mechanisms to get information out, to distribute information. I have been dealing with these issues a bit more closely and consistently and for a longer period of time than some of the folks as you move to the eastern United States. But I think there are**

**some templates out there that EPA could use to help the other States and perhaps even commodity groups or other types of non-governmental groups to get information together.**

**It's not going to be just all coming from EPA. It's not going to be just all coming from the services. It's not going to be just all coming from USDA to get the information to the people who need it. It's going to have to really be a very different way of thinking within the Federal government, a different way of thinking and engaging State government, and a different way of thinking and engaging the product groups that can also help sell the message, especially if there's a chemical out there that ultimately proves to be of concern and that we really need to watch how it's being used.**

**Also incorporating into that process the sensitivity that this issue can bring -- I hate, you know, to bring this into the regulatory context -- but the political sensitivity that not going about the communication strategy with land donors and producers the**

**right way can incur on all of us who would like to see the right thing happen both for the registration of pesticides and for preserving endangered species.**

**Things not happening the right way can make a lot of people in a lot of places get very angry and do some things that, perhaps, are disruptive to the process. And I think to not be sensitive to that, to not acknowledge it publically and to not recognize it and have to take that into consideration, whether we like it or not, and whether we like the outcomes or the people or anything else or not, on either side of the fence, is something that is short-sided and probably not in our best interest to set aside and not, you know, realize that our actions and how we go about the way we do business is going to have other ramifications in other branches of government.**

**I guess that, sort of, the combination of my third and fourth points are, you know, the recognition of process, useable formats, being adaptive, being flexible, realizing that what is comfortable for the Pacific**

**Northwest may or may not, in fact, be comfortable for, say, the regions of the south -- in the southeast, and for the Agency to be able to fill comfortable that it has the room to respond differently, to not feel like it is so rigidly being monitored and watched and has the laws of communication open with all the stakeholders to make sure that they feel like they can respond appropriately and that they can adapt how they communicate and what they communicate as long as it meets, you know, the requirements needed to get the information to the people who need it.**

**To move onto the second more long-term communication question, I'm pleased to hear both that the members of the pesticide coalition think that growers are engaged when they feel they should always be engaged, and to no fault to anyone, I think simply just a matter of trying to be expeditious and get things going. Growers do not feel always involved when they need to be involved in the process, and that's not -- it's more of a comment than it is a complaint.**

**We can be helpful earlier -- are willing to be helpful earlier -- are willing to be objective earlier. Often we are put in the position of not feeling objective and being very -- an issue comes to us that there is an issue later in the process than would be ideal for us to be helpful with resolving the issue one way or the other.**

**I don't mean saying necessarily that there's no problem. I mean saying that, what information do you need; where do you feel there are gaps. You know, there is a role that we can play and arguably, you know, the registrants are asked for more and more and more and more and more, and at some point their ability to give more and more and more and more, especially if you could get it for free someplace else for their own use and for the use of the Agency, is something that, I think, nearly all the associations that I work with representing agriculture are willing to do.**

**Now, it may take some time to get all those things set up and going early in the process, but we're willing to take the time to do that because it is**

**critically important, especially for the folks in the speciality crop industry that they maintain the ability to get new chemistries, better chemistries, safer chemistries on the market and continue to the use the ones that we know are safe.**

**The second issue on long-term process is the use of realistic and valid data, and again we hope that's something that we know the registrants have always pushed very hard for, the regulated community, being us, and our label use have always pushed very hard for, and it's something that there's have been a lot of improvements on, but we're not completely there yet. We still see and tinker with a lot of worse case scenario type evaluations, especially -- we're especially tending to see that coming out of the corps on the issue of endangered species, and that's concerning to us that, perhaps, that would set a precedent.**

**We do have concerns with how the Section 7 evaluations are done based on potential, you know, impact effect no matter how minimal or how insignificant on an**

**individual versus the maintenance of the species itself, and that probably is, perhaps, something that we would, at least, have a bit of a concern regarding the services, particularly interpretation of that and would like to see some reconciliation in the counterpart regulation between the services and the Agency on that issue.**

**Again, we would like to see all the stakeholders engaged earlier to provide the information that is needed, when it's needed, and to not be -- and to my fourth point, to not be brought into the process so late or to not be told the bad news so late that there is an outcry among our membership because we weren't able to adequately prepare them, we weren't able to adequately provide them with opportunities and alternatives, which throws into the situation of putting pressures -- you know, bringing pressures there in places that make a lot of us uncomfortable and probably don't help the process along as it is, be it through litigation or Hill action or other things like that.**

**So, it really is -- there's just a lot of**

**opportunities to communicate better and we also recognize it's going to take effort and resources on the part of the Agency to do that. And, you know, if we can get, you know, satisfactory assurances that for all the stakeholders that, you know, these improvements can be made, those are probably things that, maybe from an historical prospective, we haven't felt so supportive of that we possibly could feel more supportive of as far as getting you guys, the Agency and the services, the people and the resources they need to put the, you know, good work into play.**

**And it's great to hear what's going on in Washington State and my Farm Bureau there is very appreciative of the hard work and effort and resource allocation that you have made to that issue. And Beth's presentation is going to go into a lot of detail on some of the technical process improvements we would like to see. So, we're very pleased with both their presentations.**

**MS. CARROLL: Last night we streamlined our**

**overlays so they won't follow along with the ones you have in your packet. Looking at the time maybe that's a good thing.**

**I'm Beth Carroll and I'm representing the industries' comments on this program. I would like to thank Artie and Anne for inviting us to comment.**

**The questions, as you can see and as you have heard, are short-term, how can we be more transparent and engage the public? And we think, very definitely, that announcements of the Endangered Species Protection Program and also the advance notice of the counterpart regulations were a wonderful step in the right direction for transparency. It allowed for that transparency and for extensive public input.**

**There now needs to be a reaction to that substantive input and prompt completion, and I'm very pleased to hear from the Agency that this is going on and it's a very high priority. We, as the industry, appreciate that.**

**We would also like to say that the regulatory**

**actions that are being taken by EPA in the interim should be consistent with the Endangered Species Protection Program and with those processes outlined in the Endangered Species Act.**

**The Endangered Species Protection Program is nearly ready to be introduced. Artie wouldn't commit to a date, but I think it will be soon and with this we would like to say that the County bulletins at this point could be updated to exclude outdated information and to reflect the current label mitigations and label language. And that this should be the process that's used in the interim.**

**Existing regulatory processes must continue unimpeded and I'm hearing that from the Agency, which is also displeasing to hear. We believe that these processes can be enhanced by rule making and so, therefore, we go back to the short-term thing, to encourage that rule making to come to fruition.**

**Long-term EPA has made -- and this hasn't been a short-term process either. It's been a long-term thing.**

**But EPA has made significant clear advances in their ecological risk assessment, procedures and methods, and in the decision making that they do through FIFRA. They should continue to use public venues for scientific advancement and that includes looking at the models and processes that are being used and also science policy.**

**We would like to underline that EPA is the Agency that has the information or the data that the registrants have generated, they have the expertise to do the assessments, and they have the ability to require additional data from the registrants.**

**Existing processes with the Registration Division and the Special Review and Re-registration Division allow for prioritization of the compounds that need to go through an endangered species analysis, and the decision making that accompanies that analysis.**

**Stakeholders, and that includes everyone I think, can be more effectively engaged as we continue improvements in the long-term for a transparent process and science policy designations for the ecological --**

**endangered species assessments as a part of the ecological risk assessment, and we would like to support EPA's comments on that process as being integrated into the already existing ecological risk assessment process.**

**And any explicit endangered species data requirements and triggers for those requirements should be identified and then legally codified so that they are requirements of registration.**

**I actually got three questions from Artie and the third one was what kind of contribution do you believe that your group can provide? And so from the industries' standpoint, we did provide detailed input to the proposed rule making and EPA's Endangered Species Protection Program. So, again, we would like to see that come to fruition.**

**We believe that we can provide more information -- some of this is in your packet and handouts. We can provide more information so that more extensive scenarios can be included in the risk assessments up front in those ecological risk assessments. For example, to include**

**relevant geography; to also include typical and maximum use rates and so forth, things that would be pertinent to that assessment.**

**There is also a FIFRA Endangered Species Task Force that has developed endangered species data and that was referred to earlier, I think, by Debbie Edwards. And it's been developed under EPA guidance and this provides the best available data for the endangered species analysis as it stands currently. And, again, the best scientific and commercial data must be used and there are comments in your packet from the industry on that.**

**I think it was also mentioned that the Endangered Species Task Force has developed an information management system and it has species specific information, specific geographical information, is making use of the nature serve data and also expert opinion, and can be used very successfully in these assessments.**

**The existing FIFRA process for registration and re-registration does allow access to the registrants, technical expertise and product knowledge, and I think we**

**can continue to contribute by providing data to EPA and information to support their endangered species analyses for the compounds and we also would continue to work with the users and USDA to engage them in development of compound specific protections for the Endangered Species Act. The growers have an awful lot of information that can be used on a small scale level and a county level that would be helpful in this aspect.**

**And with that I'll close and then turn it back over to Anne.**

**MS. LINDSAY: Thank you, Beth. I have to thank all of you members of the PPDC. I know it's been a long presentation, although I will make an observation that I think every individual presenter was really very focused, very clear, and I'm hoping in the end we'll have an Endangered Species Protection Program that flows as smoothly as this whole series of presenters.**

**But I think we still have a bit of time, if I'm looking at my watch right, for questions from the PPDC members either to clarify particular things that you**

**heard or observations that you might want to make around those questions that we gave our last four presenters to look at or just other issues.**

**So, Julie, I think you were up -- well, I saw you first. I won't say that you were up first, but I'll start with you because I saw you.**

**MS. SPAGNOLI: Okay. And I have three questions. I'll try to make them quick. The first question is is the recommendation was that, you know, the Agency employed some of the provisions that they're proposing in interim decisions. What is the Agency's current, you know, interim policy? We're aware that some recent registration divisions -- or registration decisions, you know, required specific label statements. They didn't have a generic statement referring to a county bulletin. So, what is the current interim policy?**

**FEMALE VOICE: Well, obviously, we're in a state of flux a little bit in terms of --**

**MS. SPAGNOLI: Understanding that.**

**FEMALE VOICE: What we try to do in the past**

**year, in particular for new chemicals and to the extent, feasible for new uses, was to focus more attention on the endangered species issues. I mean, obviously, there are a lot of lawsuits pending and so forth. So we spent time working with the Environmental Fate and Effects Division, Artie's shop, to get those assessments, and I think if you look at the outputs for the Registration Division this year you'll see more focus on endangered species issues than you may have seen in the past that's more clearly articulated what we thought and what we did about it.**

**In some cases we were able to label off; in some cases registrants came in and proposed buffers; in some cases we worked with registrants to do other things. But I think the policy is -- probably the best way for me to describe it would be that we're trying to directionally move toward being more compliant with the Endangered Species Act and we're not there, by any means. But we're certainly working better in that direction.**

**Also in the Section 18 this year, I think, you'll see a lot more focus on making sure we're taking care of**

**endangered species issues.**

**MS. SPAGNOLI: And as the policies are finalized, that would be reflected -- you know, they go back then and apply those to some of those existing products?**

**FEMALE VOICE: We've talked about the possibility of looking at some of those through registration review. Obviously, in re-registration you would pick up those uses if you're looking at that. But to my knowledge there's no intention now to go back unless we receive a rebuttal. Those could be looked at, yeah.**

**MS. SPAGNOLI: Can I have two other quick questions and I think these are -- and this has to do with just the process of consultation. When there is consultation is there any risk benefit considerations in those consultations? In particular, if there is human health aspects?**

**MR. DYNER: The consideration for human health aspects wouldn't weigh in in the determination of whether the action is likely to jeopardize or versify.**

**MS. SPAGNOLI: And I guess if there's been a determination that there is, you know, likely effects, but then before an action is taken would, you know, let's say Center for Disease Control be consulted or if there's some human health aspects. So there's not that aspect built into the process?**

**MR. DYNER: That's correct.**

**MS. SPAGNOLI: Okay. And then the last question I have is in the implementation is there any consideration in there for consumer products -- in the proposed implementation? I didn't see it mentioned.**

**MS. WILLIAMS: Consideration meaning doing something other than what we plan on doing for other --**

**MS. SPAGNOLI: Well, other than, you know, a generic statement referring to a county bulletin. Is that what's going to be implemented for consumer products as well?**

**MS. WILLIAMS: That is what we had proposed was that all of -- regardless of what type of product it was that implementation would occur the same way where the**

**product would carry a generic statement referring people to a county bulletin. We had not considered approaching different sectors in different ways in the proposal.**

**MS. LINDSAY: I'm just going to make one quick observation, Julie. I think EPA is always going to be doing what I would call as classic risk benefit work in consultation with CDC, although as Rick correctly said in the actual endangered species consultation that's not going to have a direct role.**

**So, John, I think you're next.**

**MS. WILLIAMS: Could I say one more point on that? I think they also said earlier today that when we get a biological opinion from them we have a couple options of what to do, and if I recall, one of the options was to just go forward. So, at the tail end things like that could be considered by us as well, even though it's not built into the consultation process.**

**MS. LINDSAY: And, John, I think now we're really to you.**

**MR. VICKERY: All right. Thank you. This is**

**both a comment and observation, probably also a question, and Ms. Moran might be able to answer. So, if you could come forward.**

**It seems that one of the key issues here is that we really don't have adequate use information to do the job that we want to do. In your case, your department is getting around us by just, basically, informal consultations with anybody that can give you information so that you can do the job that you want to do.**

**You seem to have a lot of, say, regulated community support now because in most cases this allows us to get away from the worse scenario type of cases and allows us to reduce the number of false positives, if you will, and perhaps sometimes it helps us reduce some of the faults negatives too. Probably that will occur some of the time.**

**So, if you have that support and based on the way you present it you seem to have the -- you presented it in a way that industry supports this idea because it allows them to do what they want to do, not only grow**

**their crops and get their job done, but also they have an interest in protecting endangered species, too, and they want to do the right thing.**

**If that's the case, it seems that there should be the political will to get the same kind of regulation that you have in California to actually get better use recommendations. So, maybe you could say a little bit about how well this informal way of doing this is working and whether your department and industry in your State would likely support legislation at the State level to actually get the real information that you want so that you could do even a better job -- realizing that it's probably cost effective, at least the way that you presented it, right?**

**It is cost effective to give more information for you to make a better decision for the regulated community, right? And so if you would --**

**MS. MORAN: The short answer to that is the cost. In California the cost of their mandatory use reporting system runs between $25 and $28 Million per**

**year. California has in every county a County Ag Extension Agent that is the focal point of where all of the county use information is sent, at which point it is then QA'd through a quality assurance check, and then from there sent on to Sacramento for their Department of Ag's combination of all the data.**

**In Washington State we don't have that type of county level Ag Extension Agent that could be the center point for bringing the information together. While I believe that we are -- we've been successful in bringing the information from the growers to us, there is definitely still a level of concern with our growers about providing information to us because they feel concerned that any information, whether it's any data, any information always can hurt or help any situation.**

**And so I don't want to over characterize that, but they're running to us, giving it to us, although when we explain to them that regulations are coming and that we are -- we will be representing them to the best of our ability, which will likely give them a better result,**

**they are willing to participate.**

**Would they be the ones promoting legislation of use reporting? No. They wouldn't be doing that. Not in our State. I don't know what growers are like in other States as well, but our growers are willing to give the information to us because they know that we are trying to do the best thing for them. But just submitting it to -- in a computerized fashion to a State, kind of, database would be something that they would be, probably, just reticent of and the cost is really the driver there.**

**I'm sorry. Just one last quick point is that we did a use reporting trial study about four years ago and it was horribly inaccurate. A lot of the data that we got in, unfortunately, just the locations of the data -- we had applications that would appear to be occurring in the middle of the Columbia River, which we know are not the intent and not what actually occurred. But the cost of the quality assurance check of the data when it would come into the Agency is just astronomical really is in ours.**

**So, we consider our program, kind of, a counter to California's very expensive programs.**

**MS. LINDSAY: Okay. I'm going to actually go back around the table this way, starting with Larry, and come all the way around and get everybody. So, Larry, you're on next.**

**MR. ELWORTH: I think it's ironic that the Agencies had to scramble now to deal with this. When you think back to -- what was it -- the late 80s or early 90s when the Ag Committee got pretty upset about this and passed -- I guess passed an appropriations rider -- wasn't it, Jay? Preventing the Agency from implementing ESA provisions. It's kind of -- it's ironic to be in this position now having to scramble.**

**I've got a couple or three really quick questions. One is one of the big criticisms of ESA has been that when it approaches protection on a species by species basis you get protection of one species, it cross purposes with protection of another species. How is the Agency going to cross check its restrictions in one area**

**for one species and one pesticide versus the protections there providing for another species on another pesticide?**

**FEMALE VOICE: I'm not sure this is going to answer your question. (Inaudible.)**

**MR. ELWORTH: Well, you can just say that's a good question. I don't know. Yeah.**

**FEMALE VOICE: The way that we believe we must do this in order to have any of these registrations in compliance is where there is overlap of a use limitation area, if you will, that involves more than one pesticide the more stringent requirements would need to apply. There just does not seem any other way to approach that.**

**I don't know how you would get cross purposes. If I reviewed two pesticides and they're both a concern for the same species they would likely have the same limitation on their use.**

**So, I'm not sure how you would get at cross purposes. But there are many areas, even on the current bulletins that are on-line that are outdated, as was mentioned and need to be updated, areas where there are**

**multiple species in the same area and multiple pesticides some of those --**

**(End tape two, side two.)**

**MS. WILLIAMS: -- well, we have -- we actually have spent quite a few resources employing professional cartographers from the U.S. Geological Survey to update them, make them a little more user friendly, a little more understandable. They're going to be in full color, which helps in understanding. Colors are often a lot easier than multiple patch marks and patterns.**

**The ones -- and we have not actually issued any of those yet. We're redoing the ones that are on-line and then we'll update the data in them prior to issuing them as something that needs to be used.**

**I'd like to ask a question though. Anybody have any ideas on the easiest way to update those?**

**MS. LINDSAY: As we go around you can comment on those if you think you --**

**MR. JONES: Well, I'm just going to interrupt for a second. Partly it's a time issue, partly it's the role**

**of the committee. There are some in there -- time is ticking. But partly it's what we want from the PPDC, which, I think, in this context is help us think through how to engage this committee and the public more broadly in this program.**

**I mean, obviously from the questions that we're getting people have a desire for more knowledge, more understanding, more awareness, and I don't at all dismiss that. But I don't think that this is going to be the time we're going to have to answer all the questions that everybody has.**

**What we need is advice about how can the Agency interact with this committee and the public broadly on the range of issues that we presented. So, if we can focus --**

**MR. ELWORTH: That was actually my next question is how we're going to have this larger discussion? We just had the registration review. We had a workgroup on that. I know this is different because of the litigation issues. But have you all thought about how to -- or have**

**we thought about how we want to engage PPDC in answering both detailed questions, but also kind of what some of the broader policy questions are.**

**MR. JONES: Well, let me just say that I think there are two things that we struggle with here, and one is the litigation, which isn't -- you can overcome that. We have litigation in other fronts. We still talk about it.**

**And the other one is the EPA isn't always in necessarily the driver's seat. The regulations that we're developing are actually service regulations. And so trying to figure out, sort of, how you get all of the stakeholders and who are the appropriate Federal players is difficult.**

**And so you could, sort of, think about well, there are some areas that really are of purview and maybe that's where it's appropriate for us. Like how we do our assessment. And then there are other areas that are, sort of, you really need the whole Federal family if you're really going to have a meaningful discussion. I**

**think those are some of the considerations we struggled with that you, sort of, just need to have awareness of.**

**We really don't have the answer and that's really the question.**

**MS. LINDSAY: But, I guess, I would just say it would be valuable for us to hear from the committee members if you think there is a role that the PPDC could play. We may not be able to define it here this afternoon in the time we've got left clearly. But if you see some potential and that's one of the things that both and we should be exploring, that would be valuable to hear.**

**MR. ELWORTH: Well, then the reason I ask -- I bet we could go on for another hour at least with people wanting to ask questions about this, and I know you don't want to -- we got to keep moving and all.**

**But if there is that level of interest in this and these issues are, maybe, some of the more important issues as far as pesticide use over the next year or two, it would be nice to figure out a way -- I mean, Jay or**

**anybody else that might have ideas about how to engage on that, I would be real interested. I would like just to have some --**

**MR. JONES: Well, just so folks know, I've clearly taken away just from the initial dialogue here that there's a need for more information. Now, how or what we do about that, we'll have to go back and thing about. So there's a desire, clearly, for people to know more than they do. That's one take-away I think we already have.**

**MS. LINDSAY: Patti, did you have something that you thought you needed to say about this?**

**MS. BRIGHT: Actually -- you know what, I apologize. I actually need to be in Philadelphia by 5:00. So, if you don't mind, I'm just going to make my comments real quick.**

**A continuation of what we were talking about earlier in terms of how to get the environmental groups more involved. I think, Ed, in your presentation, you mentioned the fact that often times you don't have enough**

**information about endangered species. We can help you get that. We have the contacts. We have the experts.**

**One of the things that came up today and has come up in some of the earlier endangered species workshops is the fact that you don't feel like you have enough information about, perhaps, where they're located, when they're there, what they're eating. That information is extremely important, certainly, from a risk assessment standpoint.**

**And I think in addition to pointing you to the right experts, we can also point you to other resources that are out there, like the North American Bird Conservation initiative that has information about when the birds arrive in specific sections of the country, when are they breeding there, what are they doing there.**

**Certainly -- we've talked about this before -- if you're using a pesticide from August through October, maybe the only critical time for endangered species may be during the migration through October.**

**So, helping -- you know, helping you to gain**

**that information will also help to develop mitigation strategies. And so there may be times when it doesn't mean that you can't use a pesticide. It just means don't use it in this window. So, I think we could really help you with that.**

**Also, you talked a little bit about sometimes using -- or having to use surrogate species because you don't have enough information. That raises a lot of concern with me as a veterinarian. You know, if you look at dogs, all dogs are pretty much the same. They eat the same, they have the same anatomy, the same physiology with some minor differences. That is completely untrue with birds.**

**You know, if you do an necropsy or autopsy on a bird, you know, a hummingbird is going to be completely different than a duck, which is completely different than an eagle. The physiology is completely different in those birds.**

**So I really think it's important to try to get as much information about the species that you're dealing**

**with as possible. And, again, you know, we really want to work to help you do that.**

**The other thing that I would say is -- you know, talking about the proposed rule of changes, obviously the environmental groups have a different take on the way things are working than perhaps the industry groups do. But I would really encourage EPA to go back and look at some of the other projects that EPA is working on.**

**I was speaking with some people the other day about water quality issues and I know that Denise Keener at EPA is working with some people at Fish and Wildlife Service and they've developed a very effective process for looking at water quality issues. And a lot of the things that they were dealing with early on were very similar to the issues that are being dealt with here from the Endangered Species Consultation standpoint.**

**It's a pretty complicated process. EPA already had a way for doing it. How do you get Fish and Wildlife Service involved? It's interesting because there really are a lot of parallels and I think that could really**

**serve as a very good model for, perhaps, the way consultation should work between EPA and Fish and Wildlife Service or NIMS (phonetic).**

**So, I would really encourage you to, perhaps, talk to Denise about that and talk to some of the contaminant folks. I know from talking to both sides they said one of the most important things, of course, is having the right personalities that can work together on those issues. No surprise.**

**Anyway, I would -- you know, to me I think that could really be a good way to approach this. So, I apologize for jumping ahead. Thank you.**

**MS. LINDSAY: Thanks. Erik.**

**MR. NICHOLSON: I just had a couple of comments. First I was just struck that in the first two Court cases, you know, 73 pesticides did not meet the Court's scrutiny in terms of the risk assessment EPA did, which seems to me to indicate a very serious problem in the protocol that you all are using.**

**And I had a question that would follow that. I**

**think one of the specific things that -- especially in light of the discussion we had this morning, perhaps it was implicit in the flow chart that we were presented with, but it was not -- nothing about the endangered species was explicitedly mentioned in that flow chart about being one of those checklists of evaluating a pesticide's impact on endangered species as part of the re-registration process.**

**So, I would encourage the Agency to make that far more explicit.**

**The other issue, just from a worker advocate and being out in the fields for years, I have absolutely no faith without an intentional compliance plan that county specific bulletins will have any impact on pesticide use. And I think we were talking about endangered species. We have such a low threshold of space for making mistakes or intentional misuse of those pesticides that if the Agency in conjunction with USDA does not come up with a compliance plan to ensure that those guidelines are, indeed, being followed on the ground that it is useless**

**and just -- it's not even worth the paper it's printed on.**

**And finally, I think also playing up on what Patti was saying, in the outline I didn't really see anything that signifies any significant changes in how the Agency is going to do its risk assessment that would meet the scrutiny of the Court. I was just --**

**I mean, I just some comments on endangered species a couple weeks ago and I was struck that the EPA doesn't even start by requiring species specific information on impacts of pesticides on endangered species.**

**So, I'm just curious what do you all see -- and perhaps this is rhetorical question at this point in time. But specifically what changes in the risk assessment methodology do you see that you're going to implement that will meet future Court scrutiny?**

**FEMALE VOICE: This doesn't exactly answer your question. I just want to make a point about the process that we use because I think the Courts and the Plaintiffs have not said that our process is not good. What they've**

**said is that we've not carried out our process. There have not been questions about the screening level risk assessments that the Agency does for endangered species, which are the full blown assessments for registration and re-registration.**

**I think the point is that we have a process for them doing the species specific assessment, but we have not been employing that process, and that's what the Court has focused on.**

**MS. LINDSAY: Okay. Pat, I think you're up next. Sorry, corners are hard to see.**

**FEMALE VOICE: I have two thoughts, one responding to Artie's question as to how to make the bulletins available. I would say electronically and once a year for all substances -- for all chemicals should they be -- you know, that's the annual renewal date or whatever, except, of course, instances that arise that new information comes up on one particular chemical. Obviously, you don't want to wait until the October 1st or November 1st to make that known.**

**But otherwise it would be easier to just sort through by State and by County so that users know what changes, if any, apply to their particular uses. That's one thought.**

**The other thought is actually a question for Mark Dyner about the comment period for the annual notice of proposed -- advanced notice of proposed rule making. I know that you received a lot of comments and I know that it's harder to sort them out than the data.com comments because not everyone chose option three, but how are they sort of split and how has your thinking changed with, you know, having received the comments? You know, how is the Agency thinking wow, we need to start over on this aspect of our intended plan.**

**And also I know you said you couldn't give an exact time as to when you thought the proposed rule would be, but could you give us the season or something?**

**MR. DYNER: It's one of four seasons. I don't know that I can break down the comments precisely other than I think it's fairly predictably split. I think folks**

had some -- from the public interest group sides and some questions, you know, about our track record and whether the counterpart reg is appropriate. I think other folks, you know, wanted us to go forward as quickly as possible with a more efficient process for meeting our obligation.

The other question was the -- yeah. I don't think I can really give you a -- maybe other than like, as I said, it remains a high priority and, you know -- you can look at our track record on rule makings in the past and we're trying to improve on that.

MS. LINDSAY: Okay. Pat.

MR. QUINN: Well, I was going to ask one of those questions that Jim doesn't want to here, but I'll try and modify it. I guess what I took way from these really very good presentations is that this is an unbelievably daunting undertaking for all of you, and I notice that the goal is to incorporate these kinds of assessments into both registration and re-registration decisions without any sort of additional time elapsing.

And I'm wondering if, sort of, how you think how

realistic a goal that is actually. You guys may be looking at new deadlines in a fees proposal that will really put quite a bit of pressure on you in terms of turning actions around.

And I guess the -- you know, the sort of collateral question is have you thought about budgets; have you thought about how much of this gets done in-house versus out of house; and just advice to sort of get with your brothers at OMB and Interior and everybody else early on to plan for what I would think is a very significant increment of increasing your budget.

MS. LINDSAY: I think you've done a great job rephrasing your question and the answer would be yes. And I would actually -- sort of outside of this discussion -- I think we could have -- I don't mean to be flip about it, but you've pointed out a lot of the issues that we're struggling with and I appreciate the kind of perception of your remarks. If I could move onto Jay.

MALE VOICE: Well, I think Pat's suggestion to transfer funds from the Interior --

**MS. LINDSAY: Well, there are resource implications across the board, I think.**

**MR. VROOM: A couple quick questions that, hopefully, will add to the direction where the committee can help provide better advice to the Agency on this.**

**One, the services mentioned 135 days of consultation period and that it has to be agreed to by the applicant. I'm not sure who the applicant is in that parlance and, you know, is 135 days adequate? Is that the statutory language? Is it one size fits all no matter what you're talking about -- water availability decision and the kind of basin, or pesticide, or other farming practices? I'm just not clear about what that constriction is.**

**My other question has to do with other related laws. I know that we've heard that ESA trumps everything, but what happens, for instance, or theoretically or hypothetically if an endangered species pesticide convergence decision is brought in the context of an Invasive Species Act issue, and the pesticide in question**

**controls the invasive species that might threaten another endangered species or Migratory Bird Act questions.**

**You know, if we're going to get into complex matters maybe we're not at the end of this pipeline of complex issues. And how are we going to continue to bungle forward here and ruin our economy with a bunch of conflicting Federal laws that never were ever taken into consideration with one another. FIFRA and ESA may just be the tip of this iceberg.**

**I wondered if the services have any experience with some of those other acts conflicting with one another.**

**MALE VOICE: I can take the applicant question first, perhaps, and then maybe Rick can answer the other question.**

**I think under ESA -- and if you look at how that term has been traditionally interpreted, it would be hard to argue that pesticide applicants and registrants aren't applicants within the meaning of the act. The challenge, of course, is that in many instances there may be dozens**

**or, you know, hundreds of registrants for any given action and how do you involve those folks, how do you give those folks an opportunity to deal with the action.**

**I think as the term was contemplated in the Statute it was thinking about an action, like a dam building or something, where there was clearly a discrete applicant involved. But I think that's, obviously, one of the challenges that we'll have to deal with at the end as we work through the process in the NPR, for providing a public process that provides access, but that obviously can be -- how can you plead it in a manner consistent with the time period. And that kind of dovetails into that issue.**

**MR. SAYERS: With respect to the potential for conflict, there's lots of opportunity on a theoretical basis. It's surprising over the years how infrequent that it has erupted, but there have been some interesting examples, even recently.**

**The Marine Mammal Protection Act and manatees were actually in the midst of some serious conflict down**

**in southern Florida as a result.**

**In order to authorize incidental take for marine mammals you have to go through a specified rule making procedure under that authority. And until such time as that's been done, there's no ability to authorize incidental take for those species.**

**The manatee, interestingly enough, is covered by both Statutes and MTA and the Endangered Species Act. So, while we can conduct a consultation with -- typically the Army Corps of Engineers is the most common. We can conduct a consultation and we can reach the conclusion that the proposed project is not likely to jeopardize the continued existence of manatees, but we cannot authorize incidental take of that species because there is no authorization yet under MMPA.**

**The only way to fix that is to either change one of the laws or go through the rule making process. We actually tried the rule making process for MMPA and we didn't find that we could meet the standards specified. So, that's going to be an ongoing source of irritation for**

**a while yet.**

**And also another example that has popped up is in bio-control activities, particularly -- one of the species that is being used to control saltcedar. In the desert southwest we have a species that is listed called the Southwestern Willow Flycatcher. Its traditional habitats were the riparian corridors that have been overtaken by saltcedars. Unfortunately, right now in some places saltcedar is the only thing left that that bird can nest in.**

**So we're actually concerned when people come in and say gee, we want to get rid of saltcedar. We're like, okay, that's probably a good idea in the long term, but how are we going to manage through it in the short term if you actually have a successful bio-control agent.**

**So, it's not unheard of for those issues to pop up and when they do it usually requires a lot more thinking than just, you know, putting on your blinders and saying ESA rules.**

**MS. LINDSAY: Phil.**

**MR. BENEDICT: As daunting as this exercise is for the Ag community, I think it's even more daunting for the homeowner community. From a State Lead Agency point of view, we're not charged with just working with Ag communities, we're charged with forcing side laws and making sure there is compliance.**

**Have you -- I think that there are long established mechanisms to deal with the farming community. There is the Extension Service. You can usually identify farmers as commodity groups as all of those kinds of things. Those things don't occur in the homeowner community where this might apply.**

**Have you given any thought about how you're going to deal with that issue?**

**MS. LINDSAY: We're going to be brief about our thought though.**

**MS. WILLIAMS: I'm going to be very brief. I have given it thought. I don't know. That's the answer. We've not proposed anything that would -- sector. I don't know. I don't know how to effectively get to that**

**many better than you do.**

**MS. LINDSAY: That would be a broad area where I actually think we could benefit from thinking from State officials and others who actually have to, sort of, on the ground grapple with those kinds of questions.**

**Gerrett, it's your turn.**

**MR. DUYN: I'll be brief since most of my questions have been asked. That's the pain of being last in line.**

**Just one comment about the county bulletins and I don't even know if you have an answer prepared for this because it's a whole another argument in the grand scheme of this. But concerning the county bulletins there are some concerns about having entire agricultural sectors completely taken out of production.**

**In a -- (inaudible) -- like cotton or corn where there are several millions of acres this is -- it's painful to the area in which it happens, but not devastating to the industry because you probably can find some other places. But in industries such as vena-**

**culture or tree crops or extremely high valued crops in which a lot of effort and time has been sank into an agricultural area -- California would probably be the best example. If you take out a county or two counties, you could be talking several billion dollars worth of loss just at the farm gate. And if you move that further up the chain, then the number of jobs in the industries that are effected by that are pretty substantial.**

**Have you given any thought as to what kind of remediation for that damage is going to be given if something like that were to happen?**

**MS. WILLIAMS: Yeah. Actually we tried to implement just that program back in -- what was it? Early 1980 something -- when Congress told us stop. We were doing exactly that. We were saying, oh, there's a species in this county, the limitation has to apply in the county.**

**All of our effort now in these assessments and in implementing this program are to refine that geographic area in which a limitation is necessary.**

**Section 10.10 amendment to the Endangered Species Act that resulted from that debacle years ago made it very clear that we are to concern ourselves not only with complying with the Act, but with limiting the impact to agriculture and other pesticide users.**

**So, our whole goal is to refine, refine, refine, and while protecting the species put limitations in place in a small geographic area as we have to.**

**MR. DUYN: I thought earlier when there was a question concerning risk -- cost benefit analysis that the answer was no at this point?**

**MS. LINDSAY: We gave you too short an answer, I think.**

**MR. DUYN: Okay.**

**MS. LINDSAY: What I was trying to say is the EPA is going to continue to do what I would call our classic risk benefit and all of this resolution and refinement of risk and exposure to narrow impact as much as is conceivable and feasible for all of us to do. I think, Rick Sayers was trying to talk about in the**

**consultation process and the mandate of the services in implementing the Endangered Species Act it is different than EPA's mandate.**

**MS. WILLIAMS: I don't think this benefit is considered in whether we need to protect a species, but in how we can protect the species. That's kind of the distinction.**

**MS. LINDSAY: I guess the other point I would like to underscore is we're not envisioning -- for instance, if you could make a change, say, to application rate and timing on a label, and we were confident that that change would protect the species, you would not even be talking about a county bulletin.**

**So, the county bulletin is -- I guess I would call it the -- I don't want to call it that. But it's for those very, very hard cases where you really know you've got a problem and you really do have to put into place some kind of a geographic limitation.**

**It's the, sort of, solution of last resort if other things that more classically go on a label aren't**

**enough by themselves. But anything that could be dealt with by other kinds of typical label changes, you would not get to a bulletin because the goal is not to have that, sort of, gross county level impact that your constituency is concerned about.**

**Amy, I think you can close it out and let people have lunch.**

**MS. LIEBMAN: Just a follow up on what Phil said --**

**MR. JONES: Do you have mike?**

**MS. LIEBMAN: To follow up on what Phil said, it's not just compliance that has to be assured with the homeowner groups, the consumer groups, it's education of them first so that they know how to comply. And, of course, Artie knows that APSI (phonetic) has a liaison that we've established to try to make sure that we get the information from EPA early enough that we can do our educational programs for applicators and for commercial people. We all also do consumer education.**

**But I think that we need to really think about**

**how we do that education because one of the key things in providing educational program that works is to give people an understanding of why they need to do it and I don't mean because they will get a fine. You have to bring it home to them and make them understand.**

**So, I think we have to really rethink how we're going to reach that community in particular.**

**MS. LINDSAY: Okay. I think that concludes, Jim, Endangered Species.**

**MR. JONES: Thank you, all of you. I think the point -- one takeaway point is that participatory government isn't necessarily amendable to a schedule.**

**Thanks to the panel, to the people from the Agencies and from the PPDC, who participated, as well as those who came from the Washington State Farm Bureau as well.**

**Let's be back at 2:00. I know that cuts it short a little bit. I would like to ask the members of the PPDC -- I'll try to find some time before we leave, probably tomorrow as opposed to today, to get -- to try**

**to get some focused input on how and what kind of participation you would like to see around this, so we don't talk about the substance of the issue as we just did, but the participation process issues. And we'll try to find some time at the end of the session to do that. Be back at 2:00. Thanks.**

**(A lunch recess was taken.)**

**AFTERNOON SESSION**

**- - - - -**

**MR. JONES: I want to thank everybody for getting back on time. I know we had a little bit of a short lunch break, but we had a great morning and I expect we're going to have a similarly productive afternoon. If Larry were here, I could point out to him that a few minutes ago the sun actually was shining, although he doesn't take credit for that.**

**This afternoon we're starting off with a follow-up issue to an issue that PPDC began to tackle two meetings ago, probably a little over a year ago. And as I had mentioned this morning we try to fill the agenda with a combination of just general informational updates,**

**which I think our endangered species discussion was largely that, about us giving information to the members of the PPDC.**

**Teeing up issues for further deliberation, which we're going to spend some time tomorrow talking about some of those kinds of issues; and lastly, sort of in an accountability way, when we're getting advice from the PPDC about certain program areas that we're going to come back and explain, describe, discuss what we're doing with that advice. And I think actually our discussion this morning on registration review was about that, and I think that that's what our discussion on non-animal testing is about as well.**

**So let me just turn it over to Debbie Edwards.**

**MS. EDWARDS: Thanks, Jim. As Jim mentioned, we've had some prior sessions on this topic of alternatives to animal testing, and it was clear that the committee was recommending that the Agency, and particularly the Pesticide Program, focus more on this area.**

**What we're hoping today is to show you that we do have a commitment to this area. We have a pretty good panel here today to talk about various areas in which the Pesticide Program is either collaborating or possibly even had a leadership role in moving toward alternatives to animal testing.**

**We have a panel of Dr. Bill Stokes from ICCVAM; Debbie McCall from the Registration Division of Pesticide Program; Dr. Len Sauers of The Proctor and Gamble Company, and a member of the PPDC; Dr. Nancy Doerrer -- if I pronounced it correctly -- and Dr. Jack Fowle.**

**So, a lot to go through today. Let me get started by just giving Dr. Stokes a little bit of an introduction.**

**Dr. Stokes is the Director of the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods at the National Institute of Environmental Health Science, which is a component of the National Institute of Health. He's responsible for directing scientific evaluation of new**

**chemical and product safety assessment methodologies that support improved protection of improved health and improved animal welfare.**

**He also administers the Interagency Coordinating Committee on the validation of alternative methods of ICCVAM, which reviews test methods of Interagency interests and coordinates related validation, regulatory acceptance and national and international harmonization issues within the Federal Government.**

**In 1979, Dr. Stokes was awarded Doctor of Veterinarian Medicine from Ohio State University. Dr. Stokes.**

**DR. STOKES: Thank you very much, Debbie. It's a real pleasure to be here today. I was asked to give an overview of the ICCVAM committee and along with that NICEATM, which is the acronym for our NTP Interagency Center for the Evaluation of Alternative Methods. So, without further adieu.**

**I also wanted to introduce Len Sheckman**

**(phonetic). Len, are you in the room? Len Sheckman from the Food and Drug Administration serves as the Chair of ICCVAM. That's one of the 15 Agencies that participate and I just wanted to make sure that everyone was aware that Len was here.**

**What I would like to cover today is just give you an overview of ICCVAM and NICEATM, talk about our scientific advisory committee for those two organizations, talk about our nomination and submission process; just mention some of the test methods that have been evaluated by ICCVAM; and then finally talk about our collaborations with the European Center for the validation of alternative methods.**

**So, what is ICCVAM. ICCVAM is an interagency committee with designated representatives from 15 Federal regulatory and research agencies. It was originally organized by the National Institute of Environmental Health Sciences in 1994 in order to address some mandates that were given to our institute by the NIEHS Reauthorization Act in 1993. That legislation directed**

**us to develop criteria for the validation and regulatory acceptance of alternative testing methods, develop a process by which scientifically valid alternative methods could be accepted for regulatory use.**

**The committee -- an ad hoc committee, ICCVAM committee, put together those recommended criteria and processes and an outcome of that was establishment of a standing interagency committee in 1997. That committee in the year 2000 was established as a permanent government committee under the NTP Interagency Center for the Evaluation of Alternative Methods. It didn't really change what we did, but it established the committee and law with some specific responsibilities.**

**So, the agencies that are statutory members of the ICCVAM include these regulatory agencies that are listed here. There are seven of them, including the Environmental Protection Agency. Many of these agencies also carry out extensive research programs, including EPA. And then there are several other agencies that are non-regulatory, many of which have significant research**

**and testing programs.**

**So, what is NICEATM? As I mentioned, that's the NTP Interagency Center for the Evaluation of Alternative Methods. It's located at the NIEHS, at Research Triangle Park, North Carolina. There are two government staff, myself and administrative assistant, and then we're augmented with an on-site support contract of staff.**

**The center functions to administer and provide committee support and management for the ICCVAM and assure its compliance with the ICCVAM Authorization Act, Public Law 106-545. It provides both operational and scientific support for the ICCVAM working groups and expert panels, and organizes test method, peer review meetings and workshops in collaboration with ICCVAM.**

**Another function that we've taken on in the last year-and-a-half is to manage validation studies, and then finally we serve as a way to communicate with stakeholders. If individuals, organizations want to communicate with ICCVAM, they contact the center and we provide that information to the ICCVAM committee.**

**So what are the purposes of ICCVAM? These are spelled out in the ICCVAM Authorization Act and are summarized here.**

**First is to increase the efficiency and effectiveness of Federal agency test method review. This is one of the main reasons that ICCVAM was formed. Individual companies that had a new test method that they wanted to get accepted by a regulatory agency for which there were multiple agencies that the test method was applicable, would have to go from agency to agency. In the past, sometimes they got conflicting decisions about the regulatory acceptability of their test method and it also required that each time they went to an agency, individuals in that agency had to become familiar with it and --**

**So what ICCVAM does is allow all the agencies for which the test method may be applicable to, at one time, consider this new proposed method. That, in turn, eliminates unnecessary duplicative efforts and allows a sharing of expertise among the Federal agencies.**

**A third purpose is to optimize the utilization of scientific expertise outside the Federal government. We do that by including scientists from outside the Federal government on our advisory committee, on our independent expert peer review panels that we assemble, and as invited experts for workshops that we convene.**

**The committee is also charged with insuring that new and revised test methods are validated to meet the needs of Federal agencies. So, we provide guidance on what adequate validation is and what that might be for a new test method. And then the other -- finally, the last purpose is to reduce, refine or replace the use of animals in testing where feasible.**

**So, the specific duties of ICCVAM are, first, to consider petitions from the public for review and evaluation of validated test methods for which there is a regulatory application; secondly, to review and evaluate these new revised and alternative test methods; and then to develop and submit test recommendations on their scientific validity to Federal agencies. The Federal**

**agencies for which these have applicability have to respond by law within 180 days to the ICCVAM committee and ICCVAM has to make those responses available to the public.**

**The committee also provides guidance and facilitates test method development, guidance on validation criteria, validation processes. The committee also facilitates acceptance of scientifically valid test methods by virtue of this process that's in place to do a critical evaluation of new test methods. And then finally, the committee is charged with facilitating interagency and international harmonization of test methods.**

**With regard to international harmonization, when a test method comes in and goes through review by the committee, in most cases the committee will have a working group that will formulate a proposed OECD test guideline that can be considered by review and adoption by OECD, which consists of 30 member countries, including the U.S.**

**I would like to just talk a little bit about our Scientific Advisory Committee, which is required by the ICCVAM Authorization Act. The purpose in the ICCVAM Authorization Act is to advise ICCVAM and NICETAM regarding ICCVAM activities. It also includes among its membership all 15 ICCVAM agency heads or their designees. These serve as ex officio nonvoting members.**

**So, this committee was actually chartered as an NIEHS Advisory Committee and a copy of the charter was made available on the table outside this meeting hall. That charter was effective on January 9th, 2002, and the committee actually replaces an Advisory Committee on Alternative Toxicological Methods, referred to ACATM, that was established in 1997 by the Institute.**

**It's been predesignated as the Scientific Advisory Committee on Alternative Toxicological Methods or SACATM and the charter expanded its function to also NIEHS and NICEATM on NICEATM activities. It actually is composed of 15 voting members and those 15 voting members meet the required composition from the law where there**

**will be at least one representative with expertise in the development or evaluation of new, revised and alternative test methods from three different categories; the first being a personal care, pharmaceutical, industrial chemical or agricultural industry; secondly, any other industry regulated by an ICCVAM agency; and then third, a national animal protection organization established under Section 501(C)(3) of the IRS Code, which means a not for profit organization.**

**Secondly, there are representatives selected by the Director of our institute from an academic institution, State Government Agency, an international regulatory body, or corporations developing or marketing new, revised or alternative test methods, including contract laboratories.**

**This slide shows the membership of the current committee. You can see that approximately half the committee is drawn from academic institutions, but we do have representatives on there from two animal welfare organizations, the Humane Society of the United States,**

**Dr. Martin Stephens, and Dr. Peter Teheran from the Massachusetts Society for the Prevention of Cruelty to Animals, and also industry representatives. The committee is chaired by Jack Dean, who is President and Scientific Director of Signifie-Synthelabo Research.**

**This advisory committee conducts its procedures in accordance with the Federal Advisory Committee Act. All meetings are open to the public. Opportunity is provided for written and oral comments during or before the meetings; and all meetings are announced in advance in the Federal Register, as well as other means such as the ICCVAM and NTP listserves and websites.**

**There have been two meetings. The first was in December of last year and then this past August, and the third meeting is scheduled for March 9th and 10th. At the last meeting in August the committee set up two subcommittees; one on strategic planning and priority identification. So there will be reports from those subcommittees at the March meeting.**

**I would like to talk a little bit about our**

process for nominations and submissions. The committee just finalized a revision of our submission quidelines, which is pictured on this slide. It's called ICCVAM Guidelines for the Nomination and Submission of New Revised and Alternative Test Methods. There are copies of this book out on the table.

The publication provides guidance and describes the process for test method nominations and submissions. It provides an outline for the data and information needed in order to assess the test method validation status. For example --

(End tape three, side one.)

(No recording on side two.)

DR. STOKES: -- now there are no minimum submission requirements for nominations, but the more information that's provided the better the likelihood that it will be considered as a priority and there won't need to be a lot of background work done by the center in order for the method to be considered by ICCVAM and the advisory committee.

**So, some examples of these nominations might be test methods proposed for review, but that lack of complete submission package or background review document, which contains all the data, the statistical analyses of that data, that type thing. Test methods that appear promising based on limited validation data and are proposed for additional validation studies could be nominated. Test methods that have been developed, but haven't been through pre-validation or validation could also be nominated.**

**I would like to point out that nominations are likely to require resources in excess of those necessary for a technical review of a completely validated method, and so that's why we have a prioritization process. So everything that gets nominated isn't necessarily going to be carried out. It will have to be prioritized and the action on it will depend on resources available.**

**Now, the criteria that is used by the committee to prioritize test method submissions and nominations are as follows: First, is the extent to which the proposed**

**method is applicable to regulatory testing needs and applicable to multiple agencies and programs. It does not have to be applicable to multiple agencies and programs, but obviously if it is applicable to several agencies it's likely to have a higher priority than one which is only applicable to, say, one program within an agency.**

**Secondly, the extent of expected use or application and impact on human, animal or ecological health. This is, kind of, a practicality check. If the method is likely to be so expensive or so cumbersome that it can't be used by different laboratories or isn't likely to be used, then it probably wouldn't have a very high priority.**

**Thirdly, the potential for the method compared to current methods to refine animal use, that is to either decrease or eliminate pain and distress involved with the particular type of testing. The extent that it might reduce animal use or even replace animal use.**

**Fourth is the completeness of the submission**

**with regard to ICCVAM's test method submission guidelines. And finally, the potential for the method to provide improved prediction of the adverse health or environmental effect compared to current methods. Certainly this is a priority for the public health mission of our Federal agencies.**

**One more. The extent to which the test method provides other advantages, such as reduced cost and time to perform compared to current methods.**

**This is a diagram of the process for prioritizing test method submissions and nominations. Just briefly, they come into the NTP Center, which will do a preliminary evaluation on that, provide a summary for the ICCVAM Committee. The ICCVAM Committee will review that preliminary evaluation, make draft recommendations on its priority and the type of activity that would be appropriate. That will go to the Advisory Committee for their comments on priority and activities and, also, there will be the opportunity for public comment at that time on priorities and activities.**

**It goes back to the ICCVAM Committee for finalization of the priority and recommended activities. NICEATM prepares a resource requirement evaluation and then that goes to the Director of our Environmental Toxicology Program for decisions on resource allocations.**

**If it is funded, then the Director of NICEATM will inform ICCVAM of that decision, that there are resources available to initiate the activity. Typically we establish an interagency working group from the ICCVAM agencies at that point and solicit scientists within the agencies that are familiar with that particular type of toxic endpoint or methodology, and then they work with the Center to carry out the recommended activity.**

**I would just like to briefly mention some of the methods that have been evaluated. The first test method to be forwarded under the ICCVAM Authorization Act to agencies is the revised Up-and-Down Procedure for Acute Toxicity. ICCVAM recommended that this was a valid replacement for the LD50 for hazard classification purposes. The use of this test method compared to the**

**conventional LD50 test will reduce animal use by 60 to 70 percent. So, it is a fairly significant improvement in the number of animals that are required.**

**This has been accepted now by all of the major U.S. regulatory agencies, as well as adopted as an OECD test guideline.**

**The committee also held a workshop on evaluating in vitro methods that could be used to estimate or predict acute systemic toxicity in 2000. The outcome of this was that the methods were not adequately validated to serve as a replacement for animals at this point in time, but, in fact, they could be useful in establishing the starting dose for such studies.**

**The outcome of this workshop also included recommendations for research and development activities that could be carried out to advance the usefulness of these in vitro approaches. These were in the areas of screening methods, toxicokinetics, target organ toxicity and then the types of chemicals that would be useful for validation studies.**

**The ICCVAM Committee did work with the Center to put together a guidance document on how to use in vitro data to estimate starting doses. This was published -- a lot of this was based on work that was done at the German center on alternatives where they showed that there was a correlation between in vitro basal cytotoxicity and acute oral toxicity.**

**There was also post-workshop done by the institute for in vitro sciences. Roger Curran, I believe, is here somewhere, who is the President of that organization, which also helped substantiate that this would be useful for that purpose.**

**These in vitro methods, when used with -- in conjunction with the EDP can additionally reduce animal use by 30 to 40 percent.**

**This table -- I'm not going to go through all the details, but basically it shows that from 20 years ago when it took 45 animals to carry out this test that it can be with as few as three to six animals now if both the in vitro test is used in conjunction with the revised**

**up-and-down procedure. I would point out that this test probably will cost more than the conventional LD50 test, at least that's what we hear from testing labs, and it will take longer to conduct. But it does save and require fewer animals.**

**Some other test methods that we reviewed include four different types of methods for estimating the skin corrosivity potential of chemicals. If the in vitro methods predict corrosivity, a decision can be made that it's a corrosive without the use of animals.**

**The Murine Local Lymph Node Assay is a method for assessing allergic contact dermatitis potential of chemicals. This test method has many advantages. It completely eliminates the pain and distress that was associated with the previous test method, uses fewer animals and can be conducted in about a week compared to over four weeks for the previous method. And that's also been accepted by all of the U.S. Regulatory Agencies, as well as adopted as an OECD test guideline.**

**The Frog Embryo Teratogenesis Assay. We held an**

**expert panel review of this method. The conclusion was that it wasn't adequately validated for regulatory purposes, but the meeting did provide recommendations on how to improve the reproducibility and accuracy of the test method such that once that was done it might be acceptable.**

**The most recent review undertaken by ICCVAM was for four different types of in vitro, estrogen and androgen receptor assays. These are methods that are proposed for inclusion and the EPA's androgen receptor screening and testing program. Again, this meeting concluded that there were no adequately validated test methods, but they did provide recommendations that were adopted by the ICCVAM for minimal procedural standards, which we now call essential test method components that should be incorporated into standardized protocols that are brought forward for validation.**

**It also recommended a standardized list of chemicals for validation and identified priority test methods for development and validation with an emphasis**

**on non-animal sources for the receptors for those assays.**

**So, there are -- these recommendations will help facilitate validation of these methods. There are validation studies ongoing now that are incorporating this advice.**

**Finally, I'd like just to mention some of the collaborations with the European Center for the Evaluation of Alternative Methods. They're called ECVAM. Earlier this year we worked -- the ECVAM Committee worked with ECVAM to put together a joint presentation to OECD**

**-- they're a GLP working group -- recommending that there be better guidance provided on applying GLPs to in vitro toxicity testing.**

**This group met in September and agreed that further guidance should be developed. This is significant because there has not -- other than genetic toxicity testing, there has not been extensive in vitro testing done for routine regulatory submissions. So, this guidance should help provide an additional assurance**

**on how to generate data that meets the GLP requirements for agencies.**

**The ICCVAM and NTP Center are also participating on a study management team for a validation study on in vitro dermal irritation methods and contributing in the way of identifying reference chemicals for that study.**

**We also have arranged for reciprocal observer status at that ECVAM Scientific Advisory Committee, such that the Director of NICEATM and the Chair of ICCVAM attend their advisory committee meetings and the Director of ECVAM attends the SACATM meeting in the United States. And we think that that provides an opportunity to know what's going on in each area so that we don't unnecessarily duplicate efforts and that where there is the opportunity, we work together on projects.**

**We also undertaking a joint international validation study with ECVAM on in vitro methods for acute toxicity. NICEATM is a lead organization for this, but ECVAM serves, again, on the study management team, and they're funding one of the laboratories in Europe that's**

**participating. This study should be done in June of next year.**

**We also will have joint participation in upcoming workshops and peer review meetings. We just had an acute systemic toxicity workshop convened at ECVAM in September. There will be one on validation of toxicogenomic-based methods in December, and then next year there will be one on good cell culture practices.**

**I would just like to conclude by acknowledging the contributions of the scientists from the participating ICCVAM Agencies that are listed on this slide. These are the designated representatives for the ICCVAM Committee. There's 43 individuals. Obviously, EPA and FDA have more representatives because they have more extensive programs -- diverse programs, centers, different offices, divisions and this assures that we have participation from these groups.**

**I would also like to recognize the center staff at the NTP Center that work hard to support the ICCVAM's activities. And with that I'll conclude.**

**MS. EDWARDS: Okay. Thanks, Bill. Our next presenter is Debbie McCall. She's been with the EPA since 1990 and she's currently the Chief of the Technical Review Branch in the Registration Division at EPA. Her branch reviews all of the acute toxicity and product chemistry studies for conventional pesticides, as well as child resistant packaging application.**

**MS. McCALL: Hello, everyone. Let me get my slides up and I will be right with you.**

**Basically what I want to report out today on is the Science Advisory Panel meeting that just ended about 12:30 today. It was yesterday and today. We went over performance standards for in vitro methods. Basically what we were trying to do by taking this to the SAP was a consultation meeting for a way for us to incorporate these performance standards of the validated in vitro test methods that Bill just told you about for corrosivity into our guideline.**

**We ran across some legal considerations that had to be taken into account. Basically the bottom line is**

**that a government employee cannot endorse a commercial product, and what -- we have found that, at least in the beginning or at least what I project in the beginning of in vitro methods, is that people will be making them proprietary because it takes such a long time to actually put those systems and assays together.**

**And so we're seeking a way to incorporate proprietary test methods into our guidelines. In order to do that we're creating what we're calling performance standards and the performance standards are going to set forth out what we hope to be descriptive and functional attributes of the test assays and --**

**The bottom line is, sort of, like this. If it fits in this box -- if it looks like a duck and it, kind of, quacks like this duck, and it performs a whole lot like a duck or a whole lot better than that duck, we're hoping that we can incorporate it into our test guidelines.**

**Now, here are the corrosivity methods that EPA looked at with ICCVAM. Corrositex is a registered**

**product of In Vitro International; EpiDerm is a trademark of MetTek and EPISKIN is a trademark of L'Oreal.**

**So, what we're doing is we're creating essentially what we call test method components that are going to be comprised of functional, structural and procedural elements that will entail all the unique characteristics, procedural details, quality assurance, quality control measures into each performance standard. And then we will use a set of reference chemicals -- the same set of reference chemicals that were used to validate the original test method will be used for the proposed performance standard.**

**I'm not going to go into a whole lot of details, but what we're hoping to have is the same accuracy and reliability for the validated methods for our proposed methods that will come into the Agency. I've already covered that.**

**What we took to the SAP was a way to use our current GLP regulations, how Bill was talking to you about, for in vitro methods. So we talked about that**

**this morning. We're talking about how to draw on the performance standards to generic guidelines. Now, we don't have any generic guidelines written yet. We had to have the SPA meeting first. So, that's sort of our next step.**

**We want to ensure that these in vitro methods that we're looking at that they will be alternatives for animal testing for us and that they will have quality control measures built in them.**

**And at the conclusion of the meeting today at the SAP, over -- I would say overwhelming, the majority of the panel members said they endorsed the concept of performance standards. They thought it was a very good idea. Now, they did have some additional thoughts for us about ways to put them forward better, maybe additional comments on the reference chemicals and how you look at it.**

**One of the main comments that the panel had for us is looking at proposed new methods. So, we've already looked at these four validated corrosivity methods. Once**

**we've put out the performance standard there's not -- there will probably be others that will come into the Agency as a new method. They will be similar or close to what's already out there. And so our performance standards have to also cover those as well.**

**So, we look forward to having their comments back -- their full comments back, but overwhelming they were very much in favor of the performance standards.**

**MS. EDWARDS: Okay. Thanks, Debbie. Our next speaker is actually a member of the PPDC, as I mentioned before. It's Dr. Len Sauers. He's currently the Director of Product Safety, Regulatory Affairs and Analytical Sciences for The Proctor and Gamble Company. Prior to this assignment, he managed Proctor and Gamble's basic research program on animal alternatives.**

**DR. SAUERS: Thank you, and I appreciate the time to speak to the Committee today.**

**Much research has been done over the years to develop non-animal approaches to evaluating toxicity. I would say active research has been going on for at least**

**20 years. Over that time, we have had the ability to develop a lot of methods to evaluate toxicity that don't use animals. Methods involving cell culture, methods involving x-vivo tissue culture, things like that. All to look at eye irritation, skin irritation and a lot of other endpoints. And, although a lot of these methods exist, very few have undergone validation -- formal validation.**

**And as Bill just talked to you today, you can see that the process by which we need to go through to get formal validation is not very simple, and it shouldn't be simple. At the end of the day when one of these methods is accepted it is going to be used to predict safety, predict toxicity. So, it should go through rigorous validation. There should be a lot of data available to support the method.**

**But, unfortunately, this lack of validation we have for a lot of these methods is based on the fact that there isn't always a complete data set for these methods. I know for Proctor and Gamble, as we have done our work**

**internally in developing animal alternatives, we focus our data on consumer products -- cleaning products, beauty care products. Many times there is not the other data associated with other chemical classes or other products or, you know, complete data set that would be needed to take something into formal validation.**

**So, what you find is that there is a lot of methods that are available, but in most cases the data is not there or the drive to bring groups together who have the data is not there to bring it into formal validation.**

**And it's not surprising in order to get broad acceptance of any of these methods they're going to have to go through validation. No one is going to accept a method because Proctor and Gamble says it is okay. It's going to have to have broad validation by an independent group, such as ICCVAM, before it's going to have broad applicability.**

**Now, animal testing is required today to register anti-microbial formulations, especially for skin and eye irritation. But alternative methods do exist**

**today for these. There are a number of methods that are available to look at skin and eye irritation that don't require animals. These methods have not undergone formal validation and, therefore, EPA is limited in their ability to accept them. And, again, it's not surprising. I would not expect EPA to accept methods for which there has not been formal validation.**

**The responsibility they have for assuring safety is great. In order for them to take these data they have to make sure that the interpretations that are made from these data are, indeed, valid as we look at things for labeling and safety.**

**Now, ICCVAM and ECCVAM are in the process of evaluating certain alternative methods for skin and eye irritation. Unfortunately, for a lot of these methods they are looking for a broad replacement. We're taking one animal test and replacing it with an non-animal test. Unfortunately, the data is not always available, have a complete data set to support a lot of these non-animal tests.**

**Also, some of these methods are geared toward giving an answer of yes or no, especially tests around skin corrosion and eye corrosion. The conclusion from these alternative methods is does the chemical or does the formulation cause corrosivity to the skin or eye? Yes, or no. They don't have the delicacy or they don't have the sensitivity to tell us whether something is a mild irritant, a moderate irritant, a severe irritant, and that type of specificity and sensitivity is needed in order for one to make labeling decisions.**

**So, although some of these methods are coming forward for validation, they're not necessarily going to be sufficient to answer a lot of the questions we have around antimicrobial formulations for pesticide registrations. And also the timing and success of these validations is uncertain.**

**So, what I would like to propose for you today is that there is a non-animal risk assessment approach existing today for skin and eye irritation for antimicrobial formulations. Within The Proctor and**

**Gamble Company, we no longer do animal testing to evaluate the skin and eye irritation of our formulations. We spent about $160 Million over the past years to develop methods that allow us to do these assessments without the use of animals.**

**So, what I would like to propose today is instead of us trying to develop broad scale validation for these methods, looking at total replacement of animal testing for these specific endpoints, let's go through a sector specific validation, and the sector specific validation I want to put forward is for antimicrobial formulations for the endpoints of skin and eye irritation. I know today that data are available for an organization like ICCVAM or any other independent organization to look at that data set and say those methods are robust enough to make predictions on the degree of irritation and on the safety for individuals that are going to be exposed to those formulations.**

**So, can we, in essence, pick some low hanging fruit today. Not look for the grand replacement of some**

**of these animal methods for all applications, but pick off a small piece that is relevant to this group today.**

**So, what I would like to propose is that a workshop be conducted and let's look to do that, perhaps, next spring where we would bring together a group of experts in the area of skin and eye irritation alternatives. We would have group come together. I would put Proctor and Gamble's data on the table. I'm sure our competitors, who also make antimicrobial formulations will put their data on the table; we'll explain how we all do our non-animal risk assessment today; and then this group of experts would come together, review all of that and decide on formulation types and the test methods that should be used to evaluate those formulation types for irritation for skin and eye. And then out of that workshop a summary is written that is more of an instruction manual on how this non-animal risk assessment process should be done, how the test should be used, how the data are to be interpreted, both for evaluating safety and for making**

**labeling decisions.**

**After we go through this workshop, we would take the product of that, submit it to Bill and his people at ICCVAM asking them to review the conclusions of this workshop for its technical robustness and its ability for these non-animal methods to be predictive of skin and eye irritation.**

**We would then have some expectations of EPA in this process. Once we complete the workshop and this group of independent experts have come together and defined this non-animal risk assessment approach and its acceptability, we would like an interim policy to be written that would allow companies, like Proctor and Gamble and Clorox and the others, to submit these non-animal test data in support of our formulation registrations; and then once we go through the ICCVAM review and get the blessing of Bill and his people, we would look to have that policy made permanent.**

**So where do we go from here? It would be great to have a collaborative effort between EPA, ICCVAM, the**

**various stakeholders in the room to go forward with this recommendation. A subgroup can be formed to help plan this workshop, hopefully for next spring. I would be happy to be part of that planning group along with anyone else. Proctor and Gamble can provide funding and we would hope a lot of the other stakeholders and others would provide funding to identify these experts and hold this workshop.**

**MS. EDWARDS: Thank you very much. Our next speaker is Dr. Nancy Doerrer. She's the Scientific Program Manager for ILSI Health and Environmental Sciences Institute. She joined ILSI in April of 2002 and, in case -- for those of you that don't know, ILSI is a public, nonprofit organization which provides an international forum for scientists from government, industry and academia to advance the understanding and application of scientific issues.**

**DR. DOERRER: Thanks for inviting me to speak here. I want to focus this presentation on one group that ILSI HESI has been involved with working on and this**

**is the Agricultural Chemical Safety Assessment Committee. We are looking at the three R's in many context within the Health and Environmental Science Institute. The three R's being reducing, refining and replacing the use of animals. The ICCVAM Safety Assessment Group is really focused on reducing the number of animals used in testing.**

**I will mention, at the end of this brief presentation, some other groups within HESI, who are also working on reducing the number of animals used in testing. It will tend to be a longer term conclusion that they will come to based on some of their work.**

**Okay. This is the group. We call it ACSA. It's the Agricultural Chemical Safety Assessment group. This group has been very active and it's a longstanding committee. Its mission is really to bring together scientists from government, academia and industry so that they can develop some credible and viable test methods for agricultural chemical safety assessment.**

**And among the major objectives of this group is**

to reduce the number of animals that's used in testing. They believe that if testing is made more efficient, obviously you're going to reduce the number of animals. So, this group is trying to look outside the FIFRA box. We're trying not to be constrained with the kind of testing that's required under FIFRA, but what could possibly be done if you did not have FIFRA sitting there on the table as your regulation.

This is our membership and this will show to you that this group is a very multi-sector, international group. We have international organizations from Europe. We have Health Canada involved, the European Commission, OECD. We have, at least, a dozen scientists from EPA and the Office of Pesticide Programs is the strongest partner we have, but we also have EPA scientists from NCEA and from the Health Effects Laboratory and RTP.

You can also see that we have academic participation from the U.S. and abroad, and each of the major pesticide companies are involved in this project.

Okay. This is our goal and the goal was

**actually formulated when we had a public workshop a few years ago. During the public workshop the group debated for several days about what's needed in agricultural chemical safety assessment. They recommended that a flexible, tiered approach to testing be developed. And the purpose of developing a flexible, tiered testing approach would be to screen chemicals and to predict toxicity so that you don't have to go in immediately with long term chronic testing that uses a lot of animals, not really knowing what kind of results you're going to get.**

**By definition, the tiered testing approach will reduce the number of animals and possibly provide some decision points where additional testing can be waived.**

**What we did in order to get to this goal in the past -- really most of the work has been done in the past year-and-a-half -- is we formed three task forces. One is on absorption, distribution, metabolism and excretion. The ADME task force. And that group is looking at metabolic and kinetic data and how that can be incorporated into the safety assessment process.**

**Another group is the life stages task force, which is looking at vulnerable life stages and that's from prenatal exposures to the elderly populations. And then we have a systemic toxicity task force that is looking at chronic toxicity endpoints, such as carcinogenicity, neurotoxicity and all the other chronic icities (phonetic) that are out there.**

**Now, another critical element of what these task forces are looking at, and all three of them are, is an evaluation of the range of human exposure situations. By looking at this, which is not always the case when companies have to do their pesticide testing, we can look at the magnitude and route of exposure and help -- that will help in animal testing study design.**

**Okay. And as I stated, what this will help us do is develop a tiered testing approach that includes pharmacokinetic, life stages testing and systemic toxicity testing with the key criterium being that it must reduce unnecessary animal testing.**

**Okay. So, how can the number of animals be**

**reduced? And these are just a couple of examples based on the tiered testing approach that we've put together to date. These are the kinds of things that we've discovered. If you can do -- and I might add here that one of the ways that we were able to validate what we've come up with in terms of a tiered testing approach is EPA/OPP offered us their database of information that's been submitted to develop registration documents.**

**And so we looked at the reds and we looked -- we did some data mining, which helped us determine which studies show -- which studies the RFDs were actually based on. That helps us do many comparisons, like the kinds of comparisons we were able to do was how does the 28 day study compare with the 90 day dog study. The 28 day study in the rat and the 90 day dog study, which -- you know, how were these comparisons made and what kind of results turned out -- what were the RFDs based on. And this really helped us come to some conclusions about what the tiered testing approach should look like.**

**So, if we did some pharmacokinetic data**

**collection very early, you might very well get some idea about dose setting. The dose selection process would be a lot easier if you had more of that information at the beginning, and you certainly would see which species might be most relevant in your future testing in subsequent tiers.**

**When you do life stages testing in tier one one of the things that the group is debating is whether or not we could perform, say, a modified one generation study, instead of what is now required. The modified one generation not being less than what's required now, but actually adding more so that you can see in the first tier -- you can actually see more endpoints, you can actually use the animals up-front rather than, perhaps, automatically going to a two generation study, that you may not need to do based on the results that you see in a modified one generation.**

**And then in the systemic toxicity task force, they're looking at taking the typical 28 day study and adding endpoints to that. So, ultimately what you're**

**seeing here in tier one might be more animals up front, but that may actually tell you more in the long run so that you can avoid doing subsequent longer term tests with more animals in tier two.**

**So, what the group suggested was a more comprehensive 28 day study as an initial tier, and all of this -- this is only tier one and all of it could be followed up based on triggers with tier two testing.**

**Okay. The timing of what we're trying to do with this project is come back in early 2004 with the tiered testing approach and actually make it very public. We will submit the approach into the scientific peer-reviewed literature as a published document. We are going to unveil a good portion of it at the Society of Risk Analysis meeting in Baltimore in December and we're also giving a workshop on this approach in Baltimore at the Society of Toxicology meetings in March of 2004.**

**Let me just briefly mention a couple of the other activities that the Health and Environmental Sciences Institute has going on, which also will**

**contribute to the reduction of animal usage in the long run. There's three different groups. One is a structure activity relationship's database project, and that group is working with loss-eliminated. Some of you may be familiar with a database called Derek. It's used quite a bit overseas. Loss-eliminated is associated with the University of Leeds in the UK and is nonprofit organization. We're working with them to set up an international database of toxicity testing results, which includes toxicity data, physical chemical data and molecular structure information.**

**The good thing about this database is that you can search both structurally and from a substructure prospective and we have currently a pilot database that will be made available within about a month. It contains publically available information, but companies are now signing on to add proprietary information. So, I think that will be very useful in predictive toxicology.**

**Another project is the juvenile toxicity studies project and I saw that there is an announcement out on**

**the table, the registration table, for this project. There's a November workshop that we're holding. And the point of this project is to look at the need for and timing of juvenile toxicity studies and propose some new study designs and testing strategies, which once again in the long run may reduce the number of animals that are used.**

**And finally, and this is a nice lead-in to Jack's presentation, which is coming up next, we have a project on application of genomics to mechanism based risk assessment. This is an interesting project. We have a collaborative research program going on at 35 laboratories throughout the world and what they're doing is relating changes in gene expression to other measures of toxicity.**

**They're evaluating the use of GENOMICS technologies as tools for measuring toxic responses, and they're also looking at mechanisms behind toxic responses based on the results of micro-array analyses. And I'm sure as Jack will tell you this, you know, has the**

**potential for reducing animal use in the future, using all this omits (phonetic) technology.**

**MS. EDWARDS: Thanks, Nancy. Our final speaker on the panel today is Dr. Jack Fowle, who for the last year has been the Assistant Lab Director for Toxic Substances and Pesticides at EPA's National Health and Environmental Effects Research Lab in Research Triangle Park, North Carolina. Prior to that he held a number of positions at EPA, including the Deputy Staff Director for EPA Science Advisory Board and from 1992 to 1995 as Senator Moynihan's Science Advisor. Dr. Fowle received his Doctoral Degree in Genetics from George Washington University.**

**DR. FOWLE: Thank you so much, Debbie. Thanks for inviting me. I'm glad to be here to chat with you about our computational toxicology program, which is extremely important to EPA, I believe, and certainly to the Assistant Administrator for Research and Development and the Senior Management within ORD.**

**It's important to them for a number of reasons,**

**but first and foremost is the fact that this approach, they believe, will really help to provide various ways to better inform the various regulatory decisions that are made at EPA through improved risk assessment.**

**So, today what I'm going to talk about -- I'm going to open up with some of the challenges facing the Agency just to set the stage for why we believe we need this program. Then I'll illustrate some of the promises that we believe that the computational toxicology has to prioritize and rank chemicals, and also to make the testing process more efficient. We believe a major benefit of this will be the reduction and the use of animals for testing.**

**This slide shows a document, which has recently been drafted. It's being revised right now. The last I checked it was on EPA's web page, www.epa.gov/comptox. It lays out a framework for our Compto Program and there was a Science Advisory Board consultation on this on September 12th. The Science Advisory Board at that point in time said that it was a sound strategy and a good**

**starting point for these efforts.**

**It's important to note that we, within ORD, we have what we believe is a very important effort, but it's a small effort. There's certainly a lot of work underway, as we heard in ILSI and NIEHS, National Center for TOXICOGENOMIC at NIEHS, the National Center for Toxicological Research at FDA, academia, many other places -- industry. The drug industry certainly have large programs underway and we really believe we need to leverage with these activities and build on and learn from those efforts.**

**The work I'm going to describe today is the fruits of the labor from a large number of people directed by Dr. Gil Keith and Dr. Bob Kavlock of EPA.**

**This shows the risk assessment paradigm that's used at EPA was developed largely in 1983 and it's basically how we use science at EPA to inform decisions through the risk assessment process. The sense we have, however, is that you can't get there from here because it's a very costly approach, the methods to detect and**

**characterize various adverse effects use a large number of animals often, they take a long period of time. We evaluate a single chemical at a time -- with 70,000 chemicals in commerce, maybe seven or so are evaluated at various levels of -- with respect to risk.**

**If you just went through and cranked through every chemical using this kind of approach, we feel it would just be so wasteful of resources. There's got to be a better way to do it. And it's wasteful for resources both in the regulated community, certainly within the Environmental Protection Agency in terms of staffed review data and so forth, and certainly for the well-being of us all in terms of our economics.**

**We face many program challenges at EPA that prevent EPA knowing the true risk that results from exposure to various chemicals and others zena-biotics (phonetic) in the environment. EPA, since we don't know the true nature risk, we have to make assumptions about what those risks might be, so we make various policy choices. Quite often if we are not careful on how we lay**

**those policy choices out we're accused of not using sound science. So, it's very important that we use sound science at various decisions.**

**This slide lays out the key programmatic challenges the Agency faces as it implements its various programs. Certainly a better way is needed to screen chemicals to prioritize in ranking from that large list of chemicals that might be tested. Which of those are most important to test first? What should we test next? What could we reasonably feel safe with deferring for some period of time?**

**Also to identify targeted sensitive subpopulations that might be uniquely at risk that we should be quite concerned about. And thirdly, to have early prevention in mitigation of adverse outcome so we can prevent various types of exposures before they become a problem.**

**Right now EPA has different authorities. I think it has 11 major laws and three or four minor laws it must implement, and it has various approaches --**

**(End tape four, side one.)**

**DR. FOWLE: -- and the purpose of risk assessment is to organize information. Science is a Greek word, which means to organize information. So, in risk assessment we try to organize what we know about what's released into the environment, what gets into the body and what type of effects it might cause.**

**A major stumbling block to realistic risk assessment is the big gap between exposure to effect, and our challenges are we don't know the toxicity pathways, we don't know when to tail the toxicity pathways, we don't know how well the data we collect from animal tests relate to effects we can reasonably expect to occur in humans, and we don't have good structure activity models to basically look at the chemical structure and try to predict what would be a problem and what won't be a problem.**

**Another major gap we face in risk assessment is what is released into the environment, and from of the things that are released into the environment what gets**

**into our bodies, what gets into plants of concern, what gets into animals of concern and ecosystems and so forth. A lack of exposure biomarkers and more realistic models are key challenges that we face in terms of the Agency.**

**Perhaps the most important scientific challenge facing the Agency is knowing what gets into the body and where it goes when it gets in the body. I mean, after all if -- does it reach the target site? If it doesn't, there's no problem whatsoever.**

**So understanding -- what this shows -- again this shows the risk assessment processes used by EPA and it shows genomics underneath, and I'm using genomics in the broader sense of the word. Genomics really, in EPA's definition, refers to the understanding of genes and how they interact. We use two other omic words quite often. One is proteomics. It's understanding all the various proteins and what they do. And then we use the word metabolomics as well, which is looking at just the full array of metabolic activities that occur within an organism and what that might mean. We sense that if you**

**don't know what the normal biology is, it's very difficult to realistically understand how it might be altered and what the adverse effects would be.**

**So, think about it for a second. Trying to understand all the chemical reactions that occur just within one cell is absolutely staggering. But if you think about the workings of the multi-cellular, fully differentiated animal, it really starts to boggle the imagination, and all the various interaction that are occurring as cells touch each other, as hormones are released, as the nervous system interacts, as people or organisms interact socially, as hormones are released and so forth.**

**Well, we believe -- and we're not the only ones. We certainly have borrowed heavily from the drug industry for this. That a number of recent technological advances now make it possible to develop molecular profiles using the GENOMICS, proteomics and metabolomic approaches, to identify the impacts that chemicals can have on living cells and living organisms and the**

**environment. And certainly these technologies continue to change and improve, but it's no longer, we believe, a question of capability. It's how are we going to do it.**

**Parallel to the developments in genomics, there have been major advances in computer speed and access to data. I mean, less than 10 years ago trying to describe the complexity of chemical behavior was beyond the capacity of any computer -- well, all but a very few computers. Basically, we just didn't have the capacity to do it. But with advances in computer technology, we're now at the point where we can start to be able to evaluate the vast information of data that can be generated by these various omic tools using data mining techniques that have been made possible by these advances in computer capacity and speed.**

**So, when we define -- we define the word computational toxicology in EPA as integrating modern computing and information technology with the technology of modern molecular biology and chemistry to improve EPA's prioritization of data requirements and risk assessments**

**for toxic chemicals.**

**What this slide shows is that a combination of techniques, in silicon -- that would be within a computer. Silicone chip or whatever. In vitro -- I got to try to get a little humor in here -- and in vivo methods can be applied to that cascade events that goes from exposure to disease or adverse effect. We think it's critical to understand the events in this cascade because if we don't understand those events in a cascade we can't use the information to improve risk assessment process and make it more realistic.**

**So we have several overarching themes in the research and the approach that is laid out in the framework for computational toxicology. The first is that clearly they're designed to develop an understanding of that cascade of events from release of a chemical or some other anabatic (phonetic) in the environment to some adverse outcome.**

**And we believe, first and foremost, that our approach must be scientifically sound. If it's not**

**scientifically sound, if it doesn't pass peer review, if it can't be replicated, we're of zero use to the Environmental Protection Agency or the citizens of the United States.**

**Secondly, it must focus on advancing EPA's mission by developing ways to prioritize and rank chemicals for testing, and also to make the testing process more efficient. Success will be measured by coming up with more accurate, less costly risk assessment approaches and methods and models and techniques to accomplish a number of things, including the number of animals that are required for testing.**

**So, the objectives we have in our testing approach -- general objectives are, again, to improve the linkages between exposure and effect, to provide predictive models and enhance quantitative risk assessment. So what I would like to do is briefly take a look at each one of these objectives.**

**The first is a source to outcome linkage. That's on the left side of that cascade that we briefly went**

**through just a few minutes ago. And that would involve developing better chemical transformation -- understanding chemical transformation and metabolism. That includes things like chemical fate models, but also things like developing a metabolic simulator. Come up with libraries of relevant metabolic transformations that are used within computers that can develop high quality metabolic maps, and also can come up with -- as things are metabolized you can come up with substructural -- you know, it's what might their metabolism be, how might they react and so forth. Clearly that's linked with experimental biology, but we think it's important to create those in computers as well.**

**Also, exposure indicators. They are specific and sensitive and they're correlated with effects, and very importantly can be useful for assessing chemical mixtures.**

**Third, come up with dose metrics to better define toxicologically relevant doses. There might be some doses at which repair occurs or normal biological**

**process occurs so you're not concerned about what that effect would be.**

**Also characterizing toxicity pathways to understand and predict how these various unibiotics interact with biological systems. Using metabonomics to elucidate changes in metabolic patterns for a wide range of endogenous substances. If you drink a cup of coffee or eat a hotdog for lunch, you're changing your metabolic patterns, but what does that mean. You know, is that going to be of concern or not.**

**And also systems biology's approach, looking at the system as a whole to come up with computational models that can reconstruct a cell, organ or organisms components from its component parts, and it can validate and simulate experiments to build confidence in the predictive ability of chemicals and use that to predict priori what the effect might be, and then go and do the test. We want to be hypothesis based in our approach.**

**With respect to coming up with predictive models for hazard identification, clearly one important part is**

**quantitative structure activity relationship models to identify potential hazard in the absence of any kind of empirical data, to prioritize large groups of chemicals for later testing, to estimate missing perimeters from untested data amongst others.**

**Secondly, for pollution prevention strategies, try to estimate the potential impact if we're going to release this in the environment and look at various alternatives and do scenario building so, hopefully, we can do better in terms of green chemistry in evaluating the approaches that industry is developing.**

**And also clearly high throughput screening. If we have 70,000 chemicals or so in commerce, how can we just put them through some kind of high throughput screening processes to start getting at identifying which of those we should be worried about first, which can we hold off for a while and which maybe do we not have to worry about at all.**

**And then, finally with respect to enhancing quantitative risk assessment, we clearly need to better**

**define the shape of the dose response curve so we can get away from things like the linear no-threshold dose response curves for carcinogicity if it does not apply; to validate and interpret molecular indicators of exposure; to understand the importance of modes of action for risk assessment to extrapolate between species and so forth -- so on and so forth.**

**Now, what this slide shows is the proof of concept approach we've taken to launch the Compton Program, and we've selected endocrine disrupting chemicals because much is known about how EDCS interact with biological systems to cause adverse health, and Bill Stokes referred to this a little bit in the past.**

**We think that understanding the key biological pathways impacted by endocrine disrupting chemicals affords us the opportunity to design approaches to be more efficient in terms of resource utilization again in terms of our testing approaches, and to extrapolate the findings from a smaller set of chemicals to the broader chemical universe using the tools of computational**

**chemistry.**

**Bill noted that when we first went through the approach to sort of validate the endocrine disrupting chemicals it didn't work. So we've gone back and we selected a subset and we're coming up with a new training set. We're refining it. Success of approximations as we go through.**

**And so projects exploring the in silicon, in vitro and in vivo approaches could facilitate both prioritizing chemicals, reducing the need for some in vivo assays, which would reduce the number of animals required for tests, and for the in vivo assays that are utilized and that are required, have greater breadth of coverage of these various alterations, in this case endocrine alterations, or come up with better predictions of adverse outcomes.**

**We want to be relevant in our research program. If we wait five to 10 years to provide the program offices with tools or techniques they can use, we will be of little value. As I said before, science is about**

**organizing information. So, view this as success of approximation. So we're trying to design our approaches instead of coming up with near, mid and long term efforts.**

**So, I think it's not unreasonable to think, perhaps, that by the end of 2005 we would have QSAR and in vitro approaches for screening chemicals for estrogenic effects. That's certainly the target we're setting for ourselves with respect to this.**

**FEMALE VOICE: Would you say that again?**

**DR. FOWLE: By the end of 2005 have QSAR and in vitro approaches that can be used for screening for estrogenic chemicals. It won't be the Cadillac version; it won't be -- (inaudible) -- but it will be, maybe a new carburetor on the Model T or something like that. Again success of approximation.**

**Also the next steps would be to take a look at some of our existing chemical testing approaches and try to apply computational toxicology or high throughput screening processes to refine these, which would also**

**result, hopefully, in the reduction of chemical -- animals used for testing.**

**So one such approach is for the developmental neurotoxicology -- neurotoxicity, pardon me, testing approach. And again I said that the key approach is -- the point here is for us to do science for a purpose. So, we -- first of all, we're going to focus over the next one to three years on refining our current methods, trying to define alternative in vitro approaches that may be predictive of the whole animal. Midrange developed targeting testing based on predictive models -- start coming up with what some of these approaches might be and then long term, develop alternative methods that can be used as high throughput. Not, you know, one chemical every three or four months. Maybe not one chemical a week. Maybe 50 to 70 chemicals a week or more.**

**So we see long -- short term efforts to be one to three years; midrange, four to seven years; and the long term in the seven to 10-year time frame.**

**I opened by discussing some of the programmatic**

**challenges facing EPA. I would like to close with some of the challenges that face our Computational Toxicology Program. First and foremost is insuring that we do sound science. Understand the normal biological processes and cascade of events from the source of exposure through the adverse outcome so we can develop better ways to rank and prioritize chemicals for testing. I sound like a broken record, but I want to make sure I get these points across. Trying to do a better jobs of ranking and prioritizing chemicals for testing, and to make the testing process more efficient.**

**Some of our operational challenges include matching our expertise with capabilities. We are, sort of, growing up. We were trained, most people at EPA, on the standard toxicology approach. So, we have challenges and opportunities with respect to resource allocations, not just FTEs, but also a capital equipment in terms of our ability to conduct some of these experts with high bore NMRs and things of that nature. It's expensive equipment that's required.**

**Also, we need our own think tank. Right now, I mean, it might come as no surprise to you that EPA's staff is fully occupied. You know, we're sort of told to do more with lesser every year, so we clearly need to find even more ways to work smarter, faster, cheaper.**

**So, we -- and the issues we're noting today in terms of computational toxicology -- these are tough biological issues. These are issues that will win Nobel prizes depending on how things, you know, pan out. I'm not saying by EPA. It would be nice if they did, but, you know, in academia, in industry and so forth these are -- this is where biology is happening right now.**

**And so our scientists need time to think issues through. This is challenging given the demands of our time, but I think we need something like a think tank or something like that so we can get scientists, both of the program offices and also ORD, to really continue to come to grips with this.**

**Certainly, coordinating with others. As I said before two times and I'll say it again, it's just**

**absolutely critical for EPA in terms of sharing data and reaching agreement on how to interpret the data we have and put it in context. This is a really key issue.**

**We had a workshop September 29th. We brought in scientists from around the country and other parts of the world to take a look at the framework and try to help us better implement our program.**

**Interpretation, interpretation, interpretation. That cannot be underestimated. The amount of information you can generate from gene rays and so forth in a day takes months to analyze in many cases. So generating data won't be the challenge, but understanding it will.**

**And so we need scientific validation, and the scientific validation is going to need a number of things; quality assurance, that kind of stuff. I won't continue here. I think I'm running out of time a bit.**

**But harmonization is important, too, in terms of how various agencies interpret this data across -- within our own government and also with our government and**

**various other organizations internationally. We heard a bit about that from Bill and so forth. And clearly -- the harmonization, I think, also applies not just for the approaches that might be available from commercial vendors and so forth, but particularly as we're dealing with ecosystem evaluations and so forth.**

**We are dealing often times with questions that are not economically viable right now, so we cannot get large gene chip makers in some cases to make chips. So we use handmade chips and so forth. So what do we have to do to assure that these are appropriate, these are relevant, these are giving us the information we want to and so forth.**

**And so -- in terms of infrastructure, cleaning we have to think about staffing, equipment, facilities, and how we're going to attack the defaults used in risk assessment. In order to be able to use the various genomics for risk assessment we need to ensure it's scientifically valid, and the relevance -- conceptual relevance is really important to make sure we have a**

**coherent, intellectually framework that ties within that cascade of events that makes sense.**

**We have to -- approaches have to be feasible and you might think that that's technologically feasible or maybe not. This group is very sophisticated. Probably knows that -- EPA laws. It has to be feasible with EPA's laws. It has to be feasible with EPA's resources.**

**It has to be feasible with the politics, both the upper case politics on Capitol Hill and the White House, and the lower case politics. EPA managers and staff have to understand what this means and accept it. Key legislators at Federal and State level have to be comfortable with it.**

**People here. Industry has to agree. Public interest groups have to agree. General public has to accept. So, that's why it's so critical to have groups like this at meetings like this and going on beyond to try to grapple with these issues.**

**We have to understand what the data mean and we have to be able to interpret it in terms of individual**

**response and population variability.**

**So, just in summary let me just wrap up by saying we've completed the framework to guide the development of our program. The successful implementation will pose a number of challenges for us. We've had a Science Advisory Board view and a workshop to being to transition from a framework to a research program. So I look forward to discussions today and beyond and I would appreciate any help you might have. Thanks for having me.**

**MS. EDWARDS: Thank you.**

**MR. JONES: Let me make a suggestion that I would like to get feedback from the PPDC on this proposal and the flow. When we first got into this issue it was pretty narrow. It was alternative testing around acute toxicity and the Agency agreed to invest in enhancing our understanding, enhancing our efforts in this area. And when we did that we began to realize that we had a lot going on and it was much broader than acute tox and product chemistry.**

**We also found that we weren't managing it in an integrated way -- that we had a seven or eight different -- I mean, none of the things that we talked about here today just started since the PPDC, sort of, said you know, you really need to give a little more focus to this.**

**They were all ongoing, but they weren't really going on in an integrated way, and I think that we have, by paying attention to it at the advice of this group, have done a much better job of looking at it as a part of our program. We have just some short term activities going on. We have some intermediate activities and, you just heard from Jack, we have some things that are actually quite long term going on. All that really are a bit under the umbrella of alternative testing.**

**I think that the benefits from the Agency have been pretty significant in that it's increased not only our awareness, but that it's increased our management focus and we're going to see the benefits coming out of this in a more systematic way. I think we are committed**

**to maintaining our -- the level of engagement within EPA that we've had on this front.**

**So, I would like to propose that we continue to engage in the various activities that are ongoing, and I actually -- I would like to say I think that, Len, your idea of a workshop is one that we're willing to commit to participating in, which will be, sort of, new work coming out of this exercise. And that we use the PPDC as a place to come back periodically to just give brief updates, more sort of in the way in which we give other updates in five, 10, 15 minutes, just to keep the committee, in general, apprised of the progress that we're making.**

**I know at the last meeting we thought we might be going down the route of an actual subgroup -- workgroup of the PPDC and for a number of reasons. One being that there is actually a different -- another FACA that has that as its responsibility. Another reason being that I think that the engagement that we can have on this issue can and will include members of the PPDC**

**and the broader stakeholder community who want to be participating in various and sundry of these activities.**

**I don't expect those who are interested want to participate in all of them, but I am pretty sure a number of you will want to be very active in some of them and that we just use this session prospectively to come back and keep you generally posted on those activities using, you know, 10, 15 minute kind of updates. And we can also use our electronic means as well.**

**So that's what I, sort of, put on the table as a proposal for this group. I can imagine there may be a diversity of opinion around that as a follow-up and I would like to spend some time getting some feedback on that.**

**MALE VOICE: Are you also going to offer the opportunity for question to the panel or have we run out of time?**

**MR. JONES: Well, you know, this is sort of one of the struggles that we have. What the agency is often looking for is advice about paths forward and I proposed**

**a paths forward and that's what I'm looking for advice on. I think we have -- there are other ways to answer -- get your questions answered about the substance of these issues, partly because we have people here and so you can catch them. There are other ways of communicating with them. I really don't want to use the PPDC for us to just, sort of, just to learn about -- to get more knowledge.**

**So, I really would like to focus people on, sort of, I've offered a path forward. Do you think that that is an appropriate one or do you think that there is a different path forward we should pursue? Carolyn.**

**MS. BRICKEY: No, I think it is the right way to go because I think there may be some strategic points where this group can make a contribution as the work progresses. But I don't think that most of us are going to be technically savvy enough to offer the kind of, you know, detailed, technical advice that would be necessary if we had a full-blown workgroup working on this.**

**MR. JONES: Others? Julie.**

**MS. SPAGNOLI: I agree with what Carolyn said.**

**I think that really we're to the point, I think the group has pretty much agreed that this was something that the Agency should explore and I think from a policy standpoint to keep us apprised as to where the technology or where the science is as it would apply to maybe the policy. But I think we're really to the point, you know, to go forward and see what we can do, but I think it's really kind of gone beyond the technical expertise of this group.**

**MR. JONES: Pat.**

**MR. QUINN: Well, I'm shocked that people don't want to see another couple of hours on in vitro testing and particularly the eyeball outfit that we've gone over in some detail.**

**But I think it's a very fair way to proceed. I mean, I think this -- you've done a good job of focusing attention on this set of issues. I think progress is being made. I think we've heard from people around the table, both from the Animal Welfare community as well as in industry, I think an emphasis on short term progress**

**where it's possible. I mean, what Jack talked about is incredibly exciting, but probably not something that's near term.**

**And so I think we got to keep our eye on that ball and really try and see what can be accomplished reasonably in the short term. And I saw Bill nodding his head as Jack said, you know, our staff is all fully occupied. I'm sure yours is as well and you probably don't have the budget that you would like.**

**And I guess my one question, if I'm allowed, would be, you know, what Bill's advice would be about achieving things in a short term that, sort of, properly respect ICCVAM's role, but yet yield some results.**

**MALE VOICE: Well, actually that gives me a good opportunity to just mention that in the near term I think we have an opportunity to really make a significant impact on animal welfare in the area of ocular irritation.**

**I have a letter of nomination, which I think was made available to all of you, that I received on Monday**

**from EPA nominating ocular toxicity test methods for evaluation by ICCVAM. We know that four methods exist. They're screening methods that are currently used in Europe for screening. They haven't been through formal validation and the European center is interested in working together with us to take them through an evaluation process to determine if any more work needs to be done before these can be recommended for routine use.**

**If they are, then, you know, by next year -- by the end of next year, I would think that these could be implemented, if there is adequate data. If not, we would identify what data needed to be collected and we can have some near term results that will have a significant impact on animal welfare. I think that's the kind of thing that -- where we can make some progress very easily.**

**I think complete replacement is going to be -- take the path that Jack was describing. We got a lot of work to do, but there are opportunities for near term progress that I think we ought to look for those**

**opportunities and take advantage of them.**

**So, you know -- thanks for the opportunity.**

**MR. JONES: I expect that the outcome of this workshop will also help to inform that question as well.**

**MALE VOICE: I do have a question about the workshop I feel obligated to ask.**

**MR. JONES: Yeah. Sure, Al.**

**MALE VOICE: Len put an interesting concept forward about this workshop, but I wondered -- I would like to ask him, has it been vented through the trade associations that you will be able to see if there will be sufficient support from other members of the industry? P&G happens not to be a member of my association, but we normally try to put together groups of companies that have interest in things like this an bring forth these proposals. I wonder have other companies signed up for this or showed an interest?**

**MR. SAUERS: Yes. As opposed to going through the trade associations, I approached the other major formulators of antimicrobial products. So Clorox, SE**

**Johnson, Reckit and ourselves, and everybody is interested in going forward with it. And that's the key thing because people have to bring data forward. That's why it's more important to work with the companies that have the data as opposed to the trade association.**

**MR. JONES: Ray.**

**MR. McALLISTER: I think if the Agency can help coordinate the information that's available on the topic and synthesize the technical details this group can, kind of, get an overview of what's going on and we can provide some more strategic input on what we think OPP should be doing. I'm told there's OECD activities happening in this area in the next couple of weeks even.**

**I guess I have one concern I'll express now that we need to keep in mind as we go along. We're all in favor of finding better test methods and particularly where it can reduce the suffering or use of animals in those test methods. I don't want to create a whole new program that requires replacement of the testing that has been done.**

**MR. JONES: Troy.**

**DR. TROXELL: Thank you. I also agree with the previous speakers in terms of the approach that you suggested. I think that's reasonable to, you know, give it a shot and see how it goes.**

**The one area that seems to be outstanding and, you know, maybe there has been movement within EPA to correct that, but as Jack pointed out there does need to be some sort of a think tank in place to really liaise between the program offices and ORD to feed into those compu-talk (phonetic) strategy to say these are the endpoints that are of highest priority. You know, there needs to be some sort of focus and I'm not -- I'm not clear from having read the framework that there are particular endpoints that are being envisioned as the low hanging fruit or, you know --**

**I'm happy to hear that DNT is being identified, but I would like to see a list. And if there is some way that OPP could interface with ORD to actually see that this strategy in the long term identifies OPP's highest**

**priority test methods.**

**MR. JONES: We have actually begun in the last six months to engage senior management in OPP with, in particular, Jack Slav (phonetic) at the National Health and Effects Lab down in RTP in a way that we had not previously. And so those are the kinds of things we're going to talk to them about. Janine.**

**MS. RYNCZAK: I also agree with all the other people who agreed that this topic should go outside of the PPDC, I think, so that it could become broader where there is more expertise.**

**But I wanted to also -- in response to Dr. Leonard I wanted to -- I think it's right that you approach the other companies that are also involved in antimicrobials, but I think, as the other speakers pointed out, the need to reduce reliance on animals goes broader than just antimicrobials and there's a lot of expertise in Johnson & Johnson baby shampoo -- sorry to use brands or, you know, pharmaceutical companies might have a lot of ideas that they could -- they should also**

**be considered the experts in that think tank workshop group or whatever so that we're not redoubling efforts and wasting animals in the process as well.**

**MALE VOICE: Good point. Thank you.**

**MR. JONES: Jennifer.**

**MS. SASS: Thank you. I actually feel obligated to mention more of the technical points in terms of concerns of the various different NGOs and environmental groups and one of the things that Patti brought up this morning is concerns that we often, in the NGO community, have neither the resources to attend all the meetings, which is why there's only two of us here at any one time, and also the technical capabilities.**

**This morning we heard, what I considered to be, some pretty disturbing news that contrary to Patti's suggestions it appears that more and more of the -- instead of more consulting with Fish and Wildlife there is going to be more and more of the ESA type testing that will actually be embedded only with EPA.**

**That's the trend that I was hearing this morning.**

**And that the information for that will then come from the regulated industries, who will then, based on -- I think I heard whoever answers my phone calls, will then give information. To me that sounds like inside ball. I mean, that's a process that groups like mine have a lot of trouble getting any oversight.**

**And so to carry that through, what I'm hearing this afternoon is some really great advances in in vitro testing and I actually am a huge fan of this. I think it's way overdue. And I also think that the methods of in vitro testing, really although they haven't -- they're beginning to be established for a regulatory realm, have been well established in the scientific community.**

**I think -- I was trying to think when Henrietta Laxes' cancer cells were actually isolated -- it had to be 50 years ago -- to establish the first human derived immortal cell line to begin --**

**But the computational stuff concerns me and that's -- to me this carries through with what I was hearing this morning. It gets into the realm that groups**

**like mine and the NGO community has neither the technical expertise nor the financial ability to contract out to get people to participate and oversee these things.**

**In in vitro testing and setting up methods like what you were talking about, there are hundreds of thousands of people in this country that can oversee those kinds of things because it's been done for so -- you can't get through grad school anymore without having done PCR. This computational toxicology isn't like that, and I don't know how many people can oversee this kind of stuff.**

**The other thing that concerns me is in the in vitro testing in the modeling -- you're still dealing with a life system. In fact, I'm an anatomist by trade, but the biochemist consider in vivo to be within an intact cell. So, there -- I wouldn't call an intact cell a living -- you know, a complete organism, but they would and --**

**And so there's a sense that we don't really know what's going on even in science. We don't really understand initiation/progression of cancer after decades**

**of putting more money into research than any other disease endpoint in the world and in this country. And we usually don't know what's happening completely metabolically in any in vitro system, but we know what we do, we know the components that we define and we can report the output. That's what we do.**

**In this computational toxicology, correct me if I'm wrong, it's not a living system, so somebody is going to build a computer model? Help me out here. That --**

**DR. FOWLE: It is linked to living systems. The computer is one part, but clearly they'll be parallel with whole organisms, whole cells, that kind of thing to test it.**

**MS. SASS: Is it --**

**DR. FOWLE: It's hypothesis driven. You would come up with -- (inaudible) -- predictions with the computer, but then you would test it to see how it's borne out and it won't fit well all the time. So you will learn -- you will go back and you redesign your computer approach and --**

**MS. SASS: So then you'll constantly be validating by comparing with some kind of in vitro or life system. Is that considered a validation process or is that considered a constant dialectic throughout computational toxicology?**

**DR. FOWLE: I guess it depends on -- I'm not sure I quite totally understand your question, but --**

**MS. SASS: My concern is that computational toxicology is going to be like an inside ballgame trademarked, a framework that unless you have the data and the program you don't -- all you know is input and output data. That's what I'm concerned about. And what's happening with that data inside might not -- may or may not reflect a human system the way we don't -- we don't really know what's happening in the cell, but we know the output reflects what happened in the cell, even if we don't know why at all steps.**

**As a matter of fact, usually in good science we've gone beyond knowledge and we're actually surprised by what we see.**

**DR. FOWLE: Well, clearly transparency is critical in this. As I mentioned before, one of the key stumbling blocks would be the politics, both upper case and lower case P, and to the extent that, you know, groups such as yours don't accept this we're not going to succeed. So, we have to make sure that we work with you so you do understand.**

**MR. JONES: I would say, Jennifer, one of the things that I think Jack referred to is the early applications will be priority setting. And so where you're going now, priority setting by -- well, time is probably -- you know, it was 15 years ago we did it or priority setting now is alphabetical or priority setting now is a bunch of people who are smart, sitting around thinking about it. We're hopeful to have a priority setting that's much more scientifically.**

**So I think that there are interim steps that will also have transparency around it, but the early use of it will be priority setting, which I think it's hard to argue that we couldn't use a better priority setting**

**mechanism in choosing what to test first.**

**MS. SASS: So what you're telling me is basically replacing is so far down the line that I shouldn't worry about it now.**

**MR. JONES: I think you need to get engaged now so that when we're that far along you and your organization are smart enough to meaningfully participate. I think it's going to be up to you and your organization as to figure out your capacity to do that. But I think it is significantly -- I don't know -- seven to 10 years.**

**DR. FOWLE: Yes.**

**MR. JONES: Optimistic. Gerret.**

**MR. DUYN: Just to clarify, did Mr. Stokes say that you had nominated this to be reviewed by ICCVAM already?**

**MR. JONES: Well, the first step is to have the workshop and depending on what comes out of the workshop, I recall from Len's presentation, a logical next step would be to put it forward to ICCVAM. But I think you do**

**take it one step at a time.**

**MR. DUYN: Oh, I thought that's what his letter was --**

**MR. JONES: That was a different test method --**

**MR. DUYN: Okay. Well, then, that goes onto my next question then. If you're looking for more technical input on this subject, would it be in your best interest to convene a body of more technically savvy people, such as a Scientific Advisory Board of something of that nature, to discuss the matter? You know, I think that everyone is interested in seeing what this can -- what this can produce. But if we're limited by, you know, the technicalities of the issue then the people who have those technicalities need to be assembled to discuss it if you're looking for further input.**

**MR. JONES: I think that's basically what we're proposing is to have the focus around it be amongst technical people and then we just come back periodically with brief updates for strategic advice and direction.**

**MR. DUYN: Okay. And I had another question**

**maybe relating to what she's saying. This may be premature if it's 10 years down the line. But if we're looking at what effect this is going to have on how things are registered and so forth, what kind of safety assessment is going to be done with this? What kind of 10 X factor or 100 X factor, whatever, is going to be assigned to this particular procedure?**

**MR. JONES: I think those questions are way down the line, but I do think actually what we got today was when a group like this is sitting around a table seven or eight years from now we're going to be engaged in a much more meaningful way in the questions that you're -- you just asked right there.**

**MR. DUYN: Okay. We'll get to that -- we'll burn that bridge when we get to it, I guess.**

**MR. JONES: But I do think it's important for us to all have some general understanding as to the direction the Agency is going along. It's research --**

**FEMALE VOICE: Time flies when you're having fun, Jim.**

**MR. JONES: Steve.**

**MR. KELLNER: A couple things. I think there is broad support for obviously reduction of the use of animals. As far as P&G is concerned, I know that I probably went to some early meetings with them 10 or 15 years ago, so I know that you've been out there. I think there is a broad interest in the consumer community behind you and with you.**

**And in terms of low hanging fruit, I think that really does appeal to be able to get something out of this workshop. I think there's a role for the associations and perhaps screening and coming with people who would meet the criteria so that, you know, you would get a good cross group to work on the issues.**

**MR. JONES: Thanks. Phil.**

**MR. BENEDICT: I would just like to add that there's a wonderful opportunity for all the organizations out there that have data to contribute that data for chemicals and products that might be considered for reference chemicals and validation studies. That's**

**probably the most problematic issue that we have right now in moving forward in validation is identifying chemicals that we have high quality reference data from animal studies.**

**The NTP Center, on behalf of ICCVAM, issued a Federal register notice calling for data in July of this year. Unfortunately, we didn't get a very robust response. And so I would ask all of you that belong to trade organizations or have your own companies that have animal data to consider sending us data particularly for these methods that we're working on right now for dermal irritation and ocular irritation that can be considered because otherwise we're -- we're almost faced with a situation where if we don't have good representative data for the spectrum of chemical classes and product classes, it's almost impossible to carry out validation for those purposes without generating more animal data. And I don't think that's where we want to go. Certainly that would be a last resort.**

**But that's a very problematic step and I think if**

**you all are looking for a way to contribute, that that's one place that you could certainly help us out.**

**MR. JONES: Thanks. Okay. Well, this topic, I think, has been a difficult one for most of the PPDC members, myself included, because of the technical nature of it. Although I have said, I think we've moved the ball forward pretty meaningfully in this area at the Agency and I think I want to --**

**I definitely want to thank the PPDC for hanging in there with us and for those amongst you who really pushed us to focus on this. I think it has enhanced our program in a meaningful way and we'll -- I'll go forward on this issue as I described a few minutes ago.**

**All right. Let's take a 10-minute break.**

**(A brief recess was taken.)**

**(End tape four, side B.)**

**MR. JONES: Okay. We are going to engage in a couple of just updates here in this next session for our final session this afternoon. And so why don't I just turn it over -- Debbie, are you going to kick off the**

**registration and re-registration updates?**

**Ms. EDWARDS: Yes. Thanks, Jim. This is the section of the agenda where the Registration Division, the Antimicrobial Division, Biological and Bio-Pollution, BBPD, and Special Review and Re-registration Division report out on outputs for the last fiscal year. Jim has asked me to talk fast, so that's what I'm going to do. But the good news is you have handouts, so if I talk too fast you still have the information.**

**Out on the table you will see what we have fondly called a Bird Report. That does summarize the -- at least in the new use and new chemical are, the outputs for the Registration Division for FY03. Here on the slide you can see that our goal was to register 12 new active ingredients. We actually registered 14. One of those was a joint project with IR4, which we're very proud of and we did actually four joint reviews with PMRA this year on new chemicals.**

**We don't actually have a clear cut goal for new uses associated with new active ingredients, but you can**

**see there were 73 new uses there; and also new uses on existing active ingredients, or old chemicals. The goal was 230. We registered 227, which we round up and call that a success. One hundred and forty-three of those new uses were IR4 uses -- minor uses, and that actually amounts to 688 minor use clearances.**

**On the next slide you will see a little bit of a new active ingredient history for conventional chemicals, and what you will see there are the bars on the right have to do with registrations and the bars on the left for each year have to do with number of submissions of new chemicals. A couple things to note here is that this year we registered the most new chemicals since FQPA was passed in 1996.**

**And also you'll see that submission of new chemicals appear to be declining. In the last couple of years they've gone down nine, eight and then eight in 2003. So, it's hard to say yet if that's a clear trend, but there does appear to be some decline in the number of submissions.**

**This is a little bit of information about the summary of the pending new active ingredients. We're actually eating heavily into the backlog for new chemicals. In FY04 our work plan is showing candidates, 17 candidates scheduled. That is on the web now along with our new use work plan and the new chemical work plan is out on the table, if you're interested in seeing that.**

**We actually have five other new chemicals scheduled for 05 and 06. Those are NAFTA joint reviews with Canada and possibly with Mexico. That leaves really only six that we have in-house on schedule, and some of those actually, we believe, the ball is in the company's court or they have some other issues that make them -- it remains to be seen whether they'll actually get scheduled in the end.**

**As a result of this, we may be able to move more into an FY05 and 06 some assessments of these new chemicals that are actually for import only. There may be some resources available to do that.**

**In terms of inerts, in 03 seven were submitted,**

**seven were completed. Those are food use inerts. In non-food, 61 submitted, 61 completed. I know that's hard to believe, but that's the truth. But there are 57 new food use inerts pending still. That's a fairly significant backlog. We're hoping that some increased resources we received and the new methodology that's nearly final, and in fact we're already using, will improve our outputs in that area.**

**In terms of fast tracks and non-fast tracks, we ended the year, once again, the Registration Division with a zero fast track backlog. That means that nothing was over 90 days on September the 30th. A couple of interesting statistics about fast tracks, in particular. This year we completed a total of 3,447. That is essentially double what we did in the year 2000 and it's over 1,100 more than we did last year and that's due to the First State Amendment and disposal PR notice amendments that were coming in fast and furious this year.**

**In terms of Section 18, I don't think there's**

**anything particularly interesting about this table except that we are keeping our average turnaround down, which we like to see. Average turnaround in 2003 was 38 days. We essentially processed all the 18's that came in.**

**I would point out, though, and it's out on the table again, that we actually made it a priority to work on Section 3 applications for which we had longstanding Section 18s in -- to try to convert those into Section 3 uses if we could make a safety finding this year, and we actually were able to take off the books the need for 120 Section 18s during FY03.**

**Okay. Frank Sanders and Jack -- (inaudible) -- are unable to be here today, so I'm going to handle the Antimicrobial Division outputs as well. They also had a very successful year. Their goal for new active ingredients was two. They actually registered three new active ingredients. You can see the other statistics down through there. They registered six new uses. The goal was 10.**

**Then down on the next slide you'll see something**

**that -- this shows their averages, submissions and average registrations of new chemicals per year. You can see they're not quite able to keep even at their average. Submissions are 5.5, average output is 2.5. But the interesting thing there that I'm noting is they actually got 10 new active ingredient submissions in FY03, whereas in conventionals I believe we only got eight. That's kind of an anomaly for the Antimicrobial Division this year.**

**And finally these are the output reports for their fast tracks and non-fast tracks. I did look at the historical data again for Antimicrobial Division. They faced the same challenges with respect to fast tracks this year and amendments coming in in response to those PR notices. Their numbers are up significantly this year as well, but I believe they met all their goals there.**

**MS. ANDERSEN: With the biopesticides, just so you understand what that includes, they include the microbial pesticides, the biochemicals, which are stated as not having a toxic mode of action to the target pest and the plant incorporated protectants or, as we call**

**them, the PIPS.**

**We also looked -- we weren't really racing, but we had a goal of 12 and we got 14, so we're neck-in-neck with the Registration Division, in how we came out at the end. But it was a great -- it was a good year for all of us.**

**We, too, had an IR4 project that we're very excited about having it come through the system and having worked with the researcher who brought this product to the market because it will help reduce aplatoxin (phonetic) in cotton and we're pretty excited to see those kinds of real products coming out of the biologicals.**

**We tend not to count the new uses because of the, sort of, way we end up doing it, but we did have 15 associated with new AIs and 98 new uses associated with existing AIs. Also -- the next slide. You want to do that one.**

**Looking at our numbers compared to what you've seen for the others, we, too, also saw a decrease this**

**year. We've only had seven new active ingredients actually pass the screen and move on into it, but we've got a couple that are close to pending and being able to be announced, maybe even have been announced since the first of September. I know we also have just announced yesterday, we just announced a new inert that we will be considering. We do personally the inerts for the PIPs and it's an interesting one that will help us move away from some of the reliance on antibiotic resistance markers.**

**So, again, we are doing registrations at about the same level that we are actually -- or number that we're getting them in on average.**

**If you're looking at our numbers on fast tracks and non-fast tracks, like everyone else we had a lot of them coming in this year for the two PR notices and we well exceeded our goals and have more completed than we certainly have pending at this point in time. When we have non-fast track amendments I think that number is down compared to the goals probably because we didn't get**

**as many of them and that does happen to us.**

**We met or exceeded the goals for both the fast track new products and the non-fast track new products. And we also contributed to Betty's part in doing some treads and things like that, so --**

**MS. SHACKELFORD: Absolutely. Thank you. I'm going to report on where we are vis-a-vie re-registration and tolerance reassessment, and it's probably fair to say that all of the divisions, registration, antimicrobials and biological division, have all contributed to tolerance reassessment and you will see those numbers reflected in what I'm going to work through.**

**On the first slide that's an overview of what we've accomplished for this past fiscal year. We completed 28 re-registration decisions. Below that you see the breakdown. Twelve of them are REDs, three IREDs, 13 TREDs, and the specific chemicals that are in those individual categories are summarized in this -- are listed in this presentation.**

**We also completed 14 inert tolerance**

**reassessment decisions, for a grand total of 127, which moves us ever closest to our tolerance reassessment goal. Additionally, there are currently 516 uncounted tolerances and those uncounted tolerances exist because they're waiting for accumulative assessment either associated with the Ops, carbamates, triazines and such.**

**On the very next page is this listing of the REDs and I don't need to talk about that. The next page is the IREDs. The next page is the TREDs. The next page the Inerts.**

**If we go to the slide with the pie chart and the bar graph, for those of you who like things to be depicted visually, I particularly like the pie chart because essentially what it shows is that the number of the decisions that need to complete re-registration is actually decreasing. We've made quite substantial progress. There are only 155 of those decisions remaining.**

**On the right the bar graph shows where we are with regard to tolerance reassessment. And if you take a**

**quick look to the far right, that shows what our baseline is or what needs to be reassessed by the end of 2006. That number is 9,721. As of the end of September we were at 6,626. So roughly on the order about 3,100 tolerances, slightly less than that that remain to be reassessed.**

**The last page simply shows where we are on tolerance reassessment by the given grouping or categories of chemicals.**

**Debbie mentioned work plans. I do want to mention work plans as well. We don't have it here, but if there's one thing we know from the re-registration effort, folks want to know what's in the cue. Our work plan and what's scheduled for 2004 is currently on the web and we intend to update that with our plan to get through to 2006, somewhere around the end of November/end of December, somewhere around in there. So, you can look forward to that. That's really all I have.**

**MR. JONES: Any questions, comments before we take the next three updates?**

**FEMALE VOICE: Just a clarification. Does fast track automatically mean the reduced risk alternates?**

**MR. JONES: No, it's a term that we use to describe submissions to us that come without data because they don't need data.**

**For example, we asked everybody to change their first aid statement through a PR notice this year. So you submitted an amendment to change your first aid statement. You didn't need to submit any data. They're submissions that come without data basically because they don't need data. This is a term we use to describe fast track.**

**MS. ANDERSEN: So how do you get new products that are fast track?**

**FEMALE VOICE: Essentially repacks of an existing product. One company will essentially sell the right to another company to sell the identical product. In my area, in biologicals, you see in Home Garden catalogs a lot of Green Lite products and those kinds of companies. They aren't the original manufacturer.**

**They're buying that product from another BT company and selling that product.**

**FEMALE VOICE: Okay. Thank you.**

**MR. JONES: Erik.**

**MR. NICHOLSON: Sure. I had a question. I'm glad to hear that such a high number of the longstanding Section 18s went over to Section 3. Of the 344 exemptions that were granted, do you know how many are five year plus and currently ongoing?**

**MS. EDWARDS: I'm sorry. I don't know that number right here. But what I can tell you is that we made it part -- we're continuing to make it part of our prioritization for new uses because clearly what that means is that a high grower need. It kind of goes without saying. And that is part of what we consider when we set our priorities. So, once again, that was taken into account this year to set up the 370 some uses that are listed on the work plan.**

**MR. NICHOLSON: And is EPA -- I know that's been a point of contention for us and other -- EWG did a study**

**on Section 18. Is the Agency now saying five years is it and then you got to go to Section 3 or -- are you cracking down at all on that?**

**MS. EDWARDS: No. I mean, you have to have progress toward registration, you have to be an emergency -- but what -- I guess my point about that was what you don't want to have in an application for a Section 3 that's complete into the Agency and continued to issue at Section 18. I mean, that shouldn't be necessary, although things being equal so -- I mean, we're trying to make sure that if we have a Section 3 application in, it's in review if we've been issuing Section 18.**

**MR. JONES: Larry.**

**MR. ELWORTH: Just a real quick question. Is that a typical number of crisis terminations?**

**MS. EDWARDS: I believe so.**

**MR. ELWORTH: Is it?**

**MR. JONES: Yeah. All right. Thank you. Betty, you're going to do obtrusion? Okay.**

**MS. SHACKLEFORD: The final thing that I wanted**

**to give a brief update on is where we are with regard to obtrusion. As you know, we issued the interim re-registration decision for obtrusion last year -- well, this year, January 31st, 2000, through last fiscal year, and we were subject to an NRC consent decree. That consent decree required us to do two things.**

**First, it required us to consider some additional new studies that might come in specific to amphibian risks and it also required that we take a look at prostate and other cancers based on some epidemiology data that had been submitted to the Agency.**

**Over the course of this past summer, the Agency held two SAP meetings. Both of those issues were considered by the SAP. I think it's fair to say that the SAP concluded in both instances that the existing information was not sufficient to really vindicate or indict obtrusion. Where the Agency stands with those two particular issues is that there are a number of studies on -- epidemiological studies on the cancer issue that are currently being developed. It's expected that those**

**studies were completed over the next one to two years. Once those data have been completed, submitted to the Agency, the Agency intends to take that entire cancer issue back to the SAP.**

**Certainly, if any of the studies indicate that the Agency can't wait for two years to go back to the SAP, then the Agency would certainly go back to the SAP earlier, if that were warranted.**

**Similarly, on the amphibian risk issue, there are studies ongoing. Those studies are expected to be completed over the next several years and we intend to take those back to the SAP as well.**

**One thing that has, sort of, precipitated a fair amount of activity internal to EPA is a position that the Agency took in the IRED in which we identified how we wanted to treat various community level and population level risk concerns. And now I'm talking specifically about ecological risks.**

**The Agency has been working -- and when I say the Agency, the Pesticide Office has been working hand-**

**in-hand with the Office of Water to try and develop an ecological monitoring program that incorporates some of the basic tenants of the Office of Water's aquatic life criteria. That effort has really yielded some fantastic results.**

**One of the things that will happen when the Agency issues its IRED, which is scheduled to be signed on Friday, the 31st, is on or about that same time the Office of Water will come out with its aquatic life criteria and what you'll see is that the two are, in fact, harmonized.**

**The exciting thing about this particular effort is it is targeting the most vulnerable watersheds and it will allow the Agency to go in and Syngenta has voluntarily committed to do the monitoring, and if there are accedences, those accedences will be validated. They will be mitigated where appropriate consistent with the TMDL program or a program that looks a lot like the TMDL program based on measures and such that States may have in place.**

**So, it's a very, very exciting thing to be a part of. First ever, if you will, for the Agency and I think the people who have been intimately involved in that should be very pleased with the results.**

**For the IRED, and this again will be an addendum or revision to the IRED, it's going to be limited in scope to the three things that I just identified. It will set out our position on human cancer, on amphibian risks and it will have some detail on how we're going to approach the ecological monitoring program to address ecological risks. That should be completed on Friday of this week.**

**That's all I have. Any questions?**

**MR. JONES: Jennifer. I think we have one question.**

**MS. SASS: I just wanted a clarification. I didn't hear the end. You said that the IRED will be limited in scope to -- I didn't understand. To include or not include those three.**

**MS. SHACKLEFORD: Right. What we'll be issuing**

**on Friday is an amendment of the January 31st IRED and the charge for that particular document was that it would contain three elements; two of them driven by the Consent Decree and one of them set out in the IRED itself. That would be the cancer, the amphibian risk issue, and the aquatic monitoring program.**

**MS. SASS: And so those things will be amended from the 31st? So the one that comes out on Friday is going to have those three aspects amended from where they were on January 31st?**

**MS. SHACKLEFORD: The IRED will amend or update or bonafide or revise the January 31st IRED.**

**MS. SASS: On those three aspects.**

**MS. SHACKLEFORD: On those three aspects only.**

**MS. SASS: Do we have to wait until Halloween to hear what the amendments are?**

**MS. SHACKLEFORD: (Inaudible.)**

**MS. SASS: Because my press release relies on it.**

**MR. JONES: I do think this -- and actually**

**Phil, I think, recommended this at a previous PPDC that we talk about the approach to water. Once we've rolled out the decision it may be useful at some point to talk about this approach in a -- we can talk about the specifics of it, but what was interesting to me is conceptually the approach and how the approach may apply to other compounds.**

**I think what we have long been hearing from broadly the stakeholder community is that the water program, the pesticides program around issues of pesticides in water need to have some synchronicity and collaboration. I think we achieved that in this decision.**

**So, I think that that precedential part may be worth spending some time with this committee in the future talking about -- maybe something we tee up in the future. But we'll get some feedback from you all on that before the meeting is over.**

**Okay.**

**MS. SASS: One thing just popped into my little**

**fuzzy head. Because you're proposing to take the appropriate one to two years that you need to get the additional data on the amphibian and the cancer, I wonder if during that time because the issues of amphibians and possibly cancers is both endocrine disruption that you might also be considering some of the in vitro or new developing tests to look at endocrine disruption screening.**

**It was written into the original IRED that when those methods were developed that you would go back and look at non-direct binding -- endocrine disruption screening. I wonder if you are considering that?**

**MS. SHACKLEFORD: Where we are with the screening program is that the screening program is not developed to the point where we're ready to run any chemicals through it at this particular time. We're still probably a year to two -- I think I have the time frame correct -- from actually having the screening methodologies available to us.**

**So, until those methodologies are available we**

**wouldn't be able to do that, but certainly once they do become available it would seem to me that it would make some sense.**

**MR. JONES: Phil.**

**MR. BENEDICT: I'm wondering if you've considered dealing with water that's international water with regard to your watershed program and obtrusion?**

**MS. SHACKLEFORD: International water. The scope of the currently designed program is pretty much limited to flowing water bodies or watersheds.**

**MR. BENEDICT: Well, that's kind of my point. You've got the whole northern tier and across that whole northern tier you've got a lot of lakes and rivers that originate or end in another country, or are shared by two countries. And some of those actually may exceed your criteria. So, I was wondering if you have addressed that issue at all?**

**MS. SHACKLEFORD: Well, your point is well taken. What I can say is that the design of the current program, which is intended to look at 40 of the most**

highly vulnerable sites in 10 states, is intended to represent a much larger number of sites. And one of the things that the registrant has agreed to do is if you find that a particular watershed is vulnerable, you want to go back and identify what the source or what's causing that particular water body to be compromised.

Certainly that type of an initiative as it is expanded to include all watersheds, which is what it's ultimately intended to do, could, in fact, you know, get into some of the international arena. But that has not been a part -- it's not been something that we've consciously thought about now. The current focus has been on the 10 states and the 1,100 or so most vulnerable sites in the continental United States.

But, I mean, I think it's -- I think it's a very good comment and something we certainly need to think about.

MR. JONES: Thanks, Betty.

MS. LEVINE: Thank you. I'm going to give you an update on the methyl bromide critical use exemption

**process, which the division that I've been the Acting Director of for a couple of months, six months or so, has been working with the Office of Air and Radiation. The Biological and Economic Analysis Division has been working with OARs about two years now to implement a critical use exemption process for methyl bromide under the Montreal protocol.**

**And I think you were last updated shortly after we had submitted our initial nomination in February and we've just been through the first full round of technical review. We haven't still finished the first full round, but we've been through the first full round of technical review.**

**In this round we receive requests for 62 percent of the baseline -- 1991 baseline of methyl bromide to be exempt and we report through these applications and we wounded up nominating 16 sectors for critical use exemptions that represented 39 percent of the baseline for 2005.**

**Initially the MEDTOC (phonetic) came back and**

**had gave heavy cuts for most of the countries. We were one of 13 countries that submitted nominations under this process. Our initial nomination, we had 25 percent of our nomination recommended, but many, many questions and most of our nomination wasn't acted on. So, we worked throughout the summer to answer the question that the METOC had, and at the last review of the METOC, which happened, I believe, in September, they had changed their position on the way they were going to review these exemptions from a presumption against an exemption unless there was very, very solid evidence that it -- that it wouldn't work.**

**They presumed in that case that if a method -- an alternative method worked anywhere, it could work in your situation. But they flipped that at the last go-around to say that they were going to defer to the expertise of the specific country for the conditions of the nomination of the country to say that if they didn't have any specific evidence that, yes, they were clearly widespread alternatives, they would give the nomination a**

**nod. But they created a separate category from the things that were truly approved from these things that they were giving the country the benefit of the doubt and called that category noted.**

**Most countries received a mix of recommended and noted. We did pretty well. We got, you know, 33 percent of our nomination was recommendation and that was pretty good. Sixty-seven percent of our nomination was noted and it was about half a percent that was absolutely cut and that was a contingency application that we had made for sweet potatoes given the conditions in California with the telone caps. We know that telone is used, but we put in a contingency nomination and that was cut.**

**Now, I guess, the next step is going to be to go -- in Nairobi in two weeks is a meeting of the parties and there may be political discussions, but we feel that we did pretty well on our technical review around. We got 98 percent of what we requested.**

**We are currently in our second round. We've received 60 applications in 16 sectors. Again, we have**

**some new sectors that we received including cut flowers, tobacco beds, custom pesticide applicators and many additional cured ham producers applied. The total applied for was similar to last year, 62 percent of the 1991 baseline. Some of those that applied in 2005 have not yet applied for 2006 because they're sort of waiting to see what the full round after Nairobi -- what happens before they put in their nomination.**

**We think that there may be some heavy duty negotiation that has to go on. The EU, particularly the northern tier of the EU, feels that the approved requests and the noted requests were on the high end, and we may have to sort of negotiate to see how much of our actual nomination will go forward. That's being done by the Office of Air and Radiation.**

**Our current review process, it has been streamlined for people that are reapplying from last year, but we're now basing our refinements on what we learned through the first process. The measures and the things that seem to hold the most support in the METOC**

**were identifying the extent of key pest pressures, where was the nutsedge moderate to heavy and how -- what percentage of the acreage really is incorporated by that. So, we're trying to refine those data.**

**Where are there regulatory constraints? Where is there inappropriate soil, parse topography, climate problems? And we're also trying to strengthen the economic analyses. Although in the first round there was really a very heavy emphasis on technical feasibility as opposed to economic feasibility, which is, I think, part of why they created the noted category for those situations where things might be technically feasible, but not economically feasible.**

**That's sort of where we are. We hope to have our first round through -- I guess finished -- our part of it, I think by the end of November.**

**MR. JONES: Larry, and then Jennifer, and then Carolyn.**

**MR. ELWORTH: Is anybody from OPP going to be represented -- be on the delegation from the U.S. to**

**Nairobi?**

**MS. LEVINE: To Nairobi? Nobody from OPP. I think Juan Marie Peltia (phonetic) is planning to attend, but nobody from OPP is planning to attend.**

**MR. ELWORTH: Okay. Nobody from OPP.**

**MS. SASS: Carolyn, you can go first. It might cover --**

**MS. BRICKEY: So, I need to understand better what this process is about. Let's say that I grow a cumquat and I come to you and I say how did I do in this round. Do I continue my ability to use methyl bromide. You could tell me, right.**

**MS. LEVINE: Probably in a couple of weeks we'll have a better idea. At this point we know that we've made the technical arguments that have --**

**MS. BRICKEY: I mean, you can me if I'm in the 98 percent or not?**

**MS. LEVINE: Yes.**

**MS. BRICKEY: And then you're thinking maybe toward step three or four there may be some trimming**

**back. So --**

**MS. LEVINE: Yeah.**

**MS. BRICKEY: -- based on the EU's concerns, is that right?**

**MS. LEVINE: What I'm saying is the meeting of the parties have the ultimate say-so and at this point the Methyl Bromide Technical Options Committee, which does the technical review has made their recommendations and -- but there could be pushed back from the meeting of the parties to say we don't -- the noted category shouldn't be approved or that kind of a decision. Is that an accurate --**

**MS. BRICKEY: So, then what can -- if I come to you and say I grow cumquats, I want to know if I'm going to have my exemption, what can you tell me at this point?**

**MS. LEVINE: Well, can I maybe clarify -- there's got to be a follow -- (inaudible). There has to be a follow-on rule making on how it's going to be allocated. So the first step is what are the categories and the amounts that we're allowed to use. So if you submitted an**

**application for cumquats and it made it through the technical review and made it through the MEDTOC -- (inaudible) -- then there's going to be cumquats, in your particular situation, are going to be allowed to use methyl bromide. How do you -- (inaudible) -- methyl bromide and the amount, there's going to have to be some rule making. Right now there is development in the Office of Atmospheric Programs on a rule that they're expecting to publish for comment toward the end of the year or beginning of next year. So -- (inaudible) -- comment rule making on the allocation.**

**MS. LEVINE: That's assuming that the meeting of the parties doesn't change the ultimate approval. But there's -- in two weeks it's still possible that could change.**

**MS. BRICKEY: You can tell me if I passed the technical review or not.**

**MS. LEVINE: That's right.**

**MS. BRICKEY: And then you'll tell me what the other steps are?**

**MS. LEVINE: Yes.**

**MS. BRICKEY: And I'll know when exactly that I have my exemption or not?**

**MS. LEVINE: I think -- you'll know whether or not you'll have your exemption after the meeting of the parties and what they approve. Exactly how it's going to work may take a little longer, but you'll know whether or not the cumquats has been approved for 2005.**

**MS. BRICKEY: So before the end of 2004 I'll know?**

**MS. LEVINE: I think before the end of 2003 you will probably know whether --**

**MS. BRICKEY: I'll know by December.**

**MS. LEVINE: Yeah, I think so.**

**MS. BRICKEY: And then if I say to you, okay, I'm wondering, Tina, should I apply again for 2006, of course you're going to say that's your decision, Carolyn, not mine. But beyond that point what will you tell me about the chances of my getting an exemption approved in 2006? Is there going to be less methyl bromide available?**

**MS. LEVINE: Some of these things are sort of up to -- depend upon what comes out of the meeting of the parties.**

**MS. BRICKEY: Okay.**

**MS. LEVINE: I think in that in terms of the technical feasibility unless there are viable alternatives that are registered in this country we'll be able to make the same kind of technical arguments that we made in this round.**

**MS. BRICKEY: Okay. So the availability of alternatives will have a big impact on the technical argument you're willing to make. Okay. That's what I want to know. Thank you.**

**MR. JONES: Jennifer.**

**MS. SASS: So I just want to understand, when you said that you got 98 -- we got 98 percent of what we requested, is that critical use exemptions?**

**MS. LEVINE: In terms of the technical review, 98 percent of the amount of methyl bromide that we requested under critical use exemption was approved. But**

**we still have to go through the final step at the meeting of the parties.**

**MS. SASS: So, I've been talking with various different industry trade groups who are working on alternatives who want to talk to me about, you know, which alternates are safer than others, and they tell me that with the critical use exemptions that are being requested methyl bromide use will basically continue as normal in pounds for pound basis. That there is so many critical use exemptions requested that there will be no difference in methyl bromide use in this country.**

**So, what I'm hearing is EPA got a victory in getting over the first pass of avoiding the Montreal protocol. Is that right?**

**MS. LEVINE: As I said, I think what we were -- the amount that we requested was 39 percent of, I guess, the baseline. So that is a fairly high amount.**

**MR. JONES: The Montreal protocol, if the parties approve what the U.S. requested or if they don't approve of it, we will still be in compliance with the**

**Montreal protocol. We are operating within the protocols procedures. They've created a critical use exemption. That's what we're participating in.**

**MS. SASS: And according to the people that I have been talking to who are industry trade reps, everything in this country is critical use.**

**MALE VOICE: No.**

**MR. JONES: Well, I think that they requested 69 percent of the baseline in the U.S. -**

**MS. LEVINE: Thirty-nine percent.**

**MR. JONES: Thirty-nine percent.**

**MS. LEVINE: And we did not consider everything that was nominated to be critical use. I mean, we actually looked at pests -- as I mentioned, the pest pressure and where, what -- what percentage of the acreage had the most severe pest pressures, which percentage of the acreage had constraints from using the currently registered alternative.**

**I mean, at this point, you know, we put something as a critical use if there isn't a currently**

**registered alternative. There's obviously that part of the whole picture. You know, what are we doing in terms of registering alternatives that feeds into the critical use.**

**MS. SASS: I wonder if you have an exciting update for us on how you're actually replacing some of the methyl bromide in this country rather than getting exemptions and continuing its use.**

**MR. JONES: One of the challenges with that is that it's difficult to talk about the status of registration because of the confidentiality around the registration process. But we are actually working on a number of registration actions for methyl bromide alternatives.**

**MS. SASS: I hope when we have these kinds of reports we'll consider all the stakeholders at the table because some of the stakeholders here are actually interested in getting the really toxic chemicals replaced by less toxic alternatives, and I think that's something that the people around this table can, at least in**

**principle, all agree on. And I hope that when we have excited reports of our victories that those are included in our victories.**

**MR. JONES: Okay. Next --**

**MR. ELWORTH: Can I --**

**MR. JONES: Oh, sure. Larry.**

**MR. ELWORTH: I didn't interpret --**

**(End tape five, side one.)**

**MR. ELWORTH: -- presentations of scientific data and I think for that reason this is -- perfectly interested in seeing a presentation on methyl bromide alternatives and I'm especially interested, if Carolyn is applying for a critical use exemption for cumquats -- your point is well taken, but as far as the alternatives go, I think that would be an important presentation I would like to see as well. But I didn't -- I didn't see any real giddiness about the outcome. I did see some results from some pretty difficult technical work.**

**MR. JONES: Thanks, Larry. Al.**

**MR. JENNINGS: Just a quick comment. It strikes**

**me as bizarre, at best, that growers are being given permission to use an ozone depleting agent to raise a crop that when used as indicated causes cancer, heart disease and stroke.**

**MR. JONES: Okay.**

**MALE VOICE: Could we get the next -- (inaudible).**

**FEMALE VOICE: Were you referring to tobacco?**

**MALE VOICE: Tobacco, yes.**

**MR. JONES: Okay. Methyl bromide already brings out the best in all of us from my experience.**

**MALE VOICE: The representative from North Carolina speaks.**

**MR. JONES: The last topic that we're covering today came from a suggestion from some members of the PPDC. We have, in the Agency, over the last five years, I'd say, a number of times gone over some of the activities that we engage in around stewardship, or activities that we supported, efforts that we have underway, and the PPDC thought it would be useful -- some**

**members, at least, if they shared with us some of the non-governmental activities that involves stewardship.**

**And so we have a panel this afternoon that includes Jay Vroom, Carolyn Brickey and Lori Berger, each of whom are going to describe from their prospective some of the activities that they -- that their industry or non-profits engaged in that involve pesticide stewardship.**

**So, I don't know if the three of you have an order or, Jay, do you want to go first -- Carolyn, are you going to go first?**

**MR. VROOM: I'm looking forward to seeing you use this computer, Carolyn.**

**MS. BRICKEY: Okay. I'm here today to tell you briefly about protective harvest. I got some slides to present to you. It's going to go pretty fast because everybody is getting tired and they want to go home. They're getting cranky. So, I won't be able to, you know, go into elaborate detail, but there is one of our brochures or there's a stack of our brochures out on the**

**table -- the gold brochures -- and our website is listed on there, so you can spend some of your web fund looking us up and figuring out more stuff and then you can contact us if you have questions. Okay.**

**This is the agenda today, to talk about who we are, how we approach what we do and what we think we offer. Protective Harvest is a nonprofit certification organization. Our mission is to advance and certify environmentally and economically sustainable farm practices. We think our standards are very stringent, but we want them to also be transparent. Our advance activities include, of course, eco-labeling promotion and public education.**

**These are -- I've given you some examples of companies that are getting interested in sustainable agriculture. AllHome (phonetic) is the one I've chosen here and often when I talk to farm groups I tell them very sincerely that I think in three to four years if they don't come up with their own standards that they're using that the grocery companies are going to be telling**

**them what standards to us, because I can see that coming pretty -- (inaudible).**

**I'm often asked the question what do you care the most about getting your seal on a product or the environmental standard that you use? We think both of them are important. We like to have our seal on everything on earth, but that's probably not going to happen. The seal does sell the standard, which is good, but we're much more concerned about the environmental benefits we're going to get on the ground and how we can measure them, and obviously the label is secondary compared to that.**

**Our approach if to go for the maximum environmental impact and to do that we want to work with mainstream agriculture. We want to partner with grower groups or food companies so we can achieve a triple mass for change. And the way that we begin the process is to use data to establish a grower performance continuum and in the beginning of the process we want to move the poor performers on a continuum up to the higher end of the**

**scale. And we're generally talking about a three to five year process, but we want to show annual progress. I'll talk a little bit more about the continuum in the minute.**

**Everything I've read, everyone I've talked to, all the research I've done tells me that it's very important to have third party certification for what you're doing. You can speak very sincerely about what you're doing, but it's your company or your group and if it doesn't have the credibility that a third party can have in auditing and certifying the work.**

**Steps toward certification would include, as I mentioned earlier, collecting and using data to assess the practices and the use of in outs of food production; creating as performance continuant to do a comparison to see how others in the same sector performed compared to the group you're working with; and the creation of an advisory committee that's made up of members of our Board, experts that we use, experts that the grower group might use, and growers, of course, who would get involved in the process.**

**Additionally steps would include picking that starting point on a continuum where you think everybody in the group ought to be, and that's a negotiable process. It has to be realistic, it has to be a level that the growers can reach, but that's a negotiation that has to occur based on the practicality of the point that you want to choose.**

**Develop, as I said, the plan and then the Advisory Committee can work with the growers of the group to come up with standard that can be recommended to the Protective Harvest Board. That would probably take a year to complete that process. Just a guess.**

**This is an example of the toxicity unit distribution. One of the things we do in our system in Wisconsin where we certified healthy grown potatoes is use points to indicate the toxicity level of certain chemicals. We also have a list of chemicals that cannot be used and -- because of the toxicity levels of some of the chemicals that limits the number of applications or the number of times the chemical can be used.**

**And, as you can see, you got some outliers on both sides. Some very, very good and some very, very bad, and you got to wonder what those guys are going out there. But they're there in every group. So, part of the responsibility of the project is to bring those both up to par as possible.**

**This is an example of a distribution for the growers using all the different factors that are used and we call that the bio-intensive IPM score. Again, you can see that there are outliers on both sides.**

**The last steps would include the Board examining and improving the production standards with whatever modifications the Board would want to make. Then certification can begin after the participants are trained in how it's going to work. They have to learn how to use the questionnaires that we provide to develop the data, so that they can provide an annual report to our staff; and then our auditors would verify those standards have been met as part of the certification process.**

**We think we offer a credible expert organization**

**with members of our Board from mainstream environmental groups. We offer opportunities to work with recognized government and university experts, and we want to, very closely, follow the collaborative model that was used in Wisconsin to develop the standards for healthy grown potatoes because we think that's worked well; and it offers the opportunity to tell an incredible environmental story about farming, which is, as some of you know, very difficult to do. So, it's something that farmers are really interested in taking credit for what they do.**

**The kinds of environmental value would include being able to develop measurable soil and water quality standards; to develop incentive based practices; they have to tackle non-point pollution and allow farmers to take the credit for what they do there; a demonstration by farmers that they are complying with water and air regulations. For example, thousands of acres of land would be in compliance with environmental standards, which is useful, and the practices of the area doctors**

**often spread to others who aren't even participating in the projects. So I think that's a big benefit that we often don't document.**

**What about the fact that it ain't organic? Well, it's not. We're not organic. We work with mainstream agriculture. That's not to say that organic isn't a perfectly wonderful choice in the marketplace. Those of you who know me know that I was member of the National Organic Standard Board and I chaired it for two years. But this is a different approach and a different choice in the marketplace.**

**One of the advantages for a product that is produced using our standards is that it can be priced close to the conventional product and that's a huge advantage. You can educate consumers at the point of sale about what the product is and we know, based on all the polling and research that has been done, that consumers care about food safety and water quality. We think we can reach a larger segment of those people who say they'll buy groomed products by giving them**

**opportunities to buy a product that's priced closely to conventional. If that product is a high quality product and it tastes good then the consumer is going to have a good experience with it. In other words, it's a package of attributes that will determine whether or not a product is going to appeal to the consumer.**

**And our ultimate goal is to create a sustainable plan for the production of a product that can be used as a value add for the brand of the product.**

**We're currently working in Region Nine. We're develop -- we're going to be developing standards this year for two to three commodities. These are folks that we're talking to in the industry and then we hope that once we do develop standards we can proceed with some partnership and certification activities.**

**We are also beginning a project in the Midwest with Gerber and we're going to be certifying all of the crops for Gerber baby food.**

**These are five members of our Board. You may know some of these folks. I think you do. We have 10**

**members on our Board and they're very substantive involved people and we're very excited about the work that we've begun. Our project is about two years old.**

**So, that's it. Thank you very much.**

**MR. JONES: Any questions? Amy.**

**MS. LEIBMAN: Yeah. I like some of the elements of that. I'm wondering how you determine, though, toxicity? What constitutes a toxic material --**

**MS. BRICKEY: Well, we looked -- I can very quickly run out of things to say here. We look at five different factors and we put together a system that basically sets a score for each one of the pesticides that are used, and then, of course, the score would change depending on how much or how many times they're used, et cetera.**

**MS. LEIBMAN: So, there is a matrix?**

**MS. BRICKEY: Yeah.**

**MS. LEIBMAN: And --**

**MS. BRICKEY: If you look on our website there is a lot more detail there.**

**MS. LEIBMAN: Thanks. Does the seal define what it means so consumers have some indication --**

**MS. BRICKEY; What we do is we'll try to educate the consumer about what the standards are and -- one thing I forgot to mention, which is really important, is that we have a chain of custody so that we can show that the food that's in the box that you're buying was produced using the standards that we're telling you about.**

**MR. JONES: Julie.**

**MS. SPAGNOLI: Just looking for a little bit of clarification. So this is really, kind of, the commodity-by-commodity approach that --**

**MS. BRICKEY: As opposed to processed food?**

**MS. SPAGNOLI: Well, no. I think as opposed to just having an overall -- when you're saying what the standards -- the standards are applied on a commodity-by-commodity approach?**

**MS. BRICKEY: Yes.**

**MS. SPAGNOLI: And not -- there's not just one overlying standard.**

**MS. BRICKEY: No.**

**MS. SPAGNOLI: I'm just looking for clarification. Thanks.**

**MS. BRICKEY: Anything else? I would like to introduce Rochelle Calvin. She's our Deputy Director and she keeps me from going too far off the track. Bob.**

**MR. ROSENBERG: Yeah. Carolyn, do you market the brand to food processors or to the public in general or both?**

**MS. BRICKEY: We're very interested in working with food processors and we've, obviously, started in that direction just because they can help drive the process with growers and they can also help pay for some of the work that needs to get done.**

**MR. ROSENBERG: But not the consuming public directly? I mean, do you --**

**MS. BRICKEY: I think, you know, doing public education, quote/unquote, is incredibly expensive. People pay millions of dollars to do that every year and we would rather have our clients do that for us. Anybody**

**else?**

**MR. JONES: Thanks, Carolyn.**

**MS. BRICKEY: Thank you all very much. It's a pleasure to bring this to the table.**

**MR. JONES: Thanks. Jay.**

**MR. VROOM: (Inaudible) -- Lori is ready.**

**MR. JONES: Lori, okay.**

**MR. VROOM: I don't think she's got any power point slides and I can get mine --**

**MR. JONES: Okay. That would be great.**

**DR. BERGER: Okay. This will be really quick because I just found out about it a couple days ago. I'm glad I'm not the last one because the group is getting a little bit grumpy.**

**My name is Lori Berger. I sit on PPDC. I'm with an organization called the California Minor Crops Council, which is -- it's a coalition of specialty crop commodity groups and I just wanted to share some of the good news things that are going on with our commodities. We tend to focus on a lot of the negative, really heavy**

**issues and there are, in fact, some very positive things going on that a lot of the grower groups I'm working with are directly involved with.**

**Just to back up a little bit, the organizations I work with are generally called marketing orders and these are grower organization groups that basically -- they tax themselves for the purposes of promoting their commodity and also conducting research and education program. And, as we move through FQPA and deal with a lot of the things we talk about here at PPDC, these types of organizations are really key as we try to transition to reduced risk pest management, which is basically what the minor crops council is all about.**

**And so I just wanted to mention some of the interesting projects that are going on in some of the commodities that I work with, and I'm not going to mention all 16 of them because we're at the end of the day. But just, for example, pears, they've had an excellent program working on the use of what are called pheromone puffers. These are pheromone releasing devices that they put out**

**in the orchard and it's used for mating disruption, and through the use of these reduced risk products they've been able to reduce the use of organophosphates up 50, 60 percent in orchards. It has been highly, highly successful.**

**Also in stone fruit, peaches, plums and nectarines, in one of the groups I work for is one of the ones that's working with Carolyn -- did Carolyn leave? No. She's back there talking. I'm talking, Carolyn. I listened to you.**

**Anyway, also the stone fruit people are very involved in reducing the amount of OPs. This is of great concern because, as we all know, peaches, plums, nectarines are -- they factor high in the diets in infants and children, which was a real target for FQPA. They've also been very successful in the use of pheromones.**

**Also, from an environmental quality standpoint we've been able to move away from the use of dormant applications of pesticides, which are actually -- using**

**pesticides during the dormant season is a real positive in that you're using effective materials at a very weak point in the life cycle of certain insects and also you are making applications when there's on produce on the tree and there are very few, if any, workers in the orchard.**

**The good news is that we've been able to get away from a lot of the organophosphate applications that were major in this time and move to just the use of oils, which has been very, very effective.**

**Also in kiwi fruit, we've moved to some reduced risk material for botrytis, which is a very important post harvest disease, that was just granted very recently on a Section 18. We've very, very pleased about that. It replaced a B2 carcinogen.**

**In prunes, also known as dried plums, we have integrated a farming system program that works with growers one-on-one having to do with dormant application and water quality issues, and that's been very, very successful.**

**Strawberries has an active program. Methyl bromide has been brought up. Strawberries is very dependent upon methyl bromide, but I guarantee you that they are -- they have a very active grower's supported research and education program to move away from the use of methyl bromide.**

**Along those lines -- that material, it is a critical use for that industry and many others. Even the organic strawberry growers depend upon the use of methyl bromide to develop disease-free and pathogen-free planting stock for organic nurseries. So they also had a critical use exemption in. Another thing that our groups are working with, we are working with the University of California on a train to trainer program to educate workers on reduced risk practices.**

**So all the groups I work with are very active on both research and education programs. These are very highly collaborative projects with the University and with Cooperative Extension. Of course, in a State like California and all states we're very, very concerned about**

**our State resources. As we move to products that are more technical -- they're more complicated to use in many ways, we are really dependent upon working with our University and Extension people. So, we're very concerned about the State budgetary situations and how this is going to impact how our growers transition reduced risk. So, that's something that's very much on our minds these days.**

**And then finally I just wanted to briefly touch on the fact that grower groups are not just taking pest management on a pest-by-pest basis. We are working on, what are called, pest management strategic plans, which are long range overviews of the issues that our growers are going to face. We are identifying the key research, regulatory and educational needs to move towards reduced risk. We are very likely going to be weaving into our strategic plans natural resources management issues -- air, water, endangered species.**

**So, we are taking the long view on these things and there are some good things happening out there. So,**

**that's my story and I'm sticking to it.**

**MR. JONES: Thank you, Lori. Any questions? Comments? Jennifer.**

**MS. SASS: Thank you. I liked that talk.**

**MS. BERGER: Thanks. Anybody else?**

**MR. JONES: All right. Thanks, Lori. Jay.**

**MR. VROOM: Thanks, Jim. Let me introduce myself quickly for those of you that I have not met. I'm Jay Vroom, President of CropLife America. My organization represents about 70 members that account for the vast majority, probably 98-99 percent of all the crop protection and crop biotechnology products used by American farmers and we are also closely affiliated with RISE, who have been represented here today, but Allen James is gone by now. So, I guess I can say anything I want about RISE as well.**

**But I think that I had something to do with the idea of having this session originally and I appreciate the opportunity for these presentations to come before the PPDC because I still believe that there is a lot of**

**good news about what all of us in agriculture and non-agriculture pesticide user community do with regard to stewardship, and it has a lot of implications and variations of meaning.**

**Many of the other associations representative of the industry for pesticides, various aspects, returns a lot. I notice that Dr. Kellner has a brochure from CSPA available for all of us that talks about their stewardship commitments. I know CPDA, RISE and many of the other groups here representing industry share various commitments and resources to stewardship, and all of us work with our customers and have a lot to do from the industry's applied standpoint in supporting the kinds of things that, in fact, Carolyn and Lori have talked about as well.**

**So, I have, I think, 21 slides. My original idea was that CropLife Director Stewardship, Tom Holley, would make this presentation, but since he had plenty of warning he was able to manufacture some other important trip and left me with this presentation which he**

**developed. So, at about five minutes a slide I think we're going to be late for dinner tonight.**

**The good news is --**

**MALE VOICE: Not all -- (inaudible).**

**MR. VROOM: The good news is in sense of time it would appear it won't take five minutes a slide.**

**We like to use this kind of a life cycle illustration for the industry's commitment to stewardship, not just here in the United States, but throughout our Crop Life international network of associations around the globe. And I'll talk about some of the critical pieces to this as we go forward here.**

**The first piece has to do with manufacturing standards for crop protection chemicals and we've accomplished that by the way of working through the American Chemistry Council's responsible care program. Steve, I think CSPA's program is a derivative of the responsible care program at ACC. It's your own version for the kind of products that CSPA members developed and sell in the marketplace.**

**CropLife America is a responsible care partner association and I have copies of these slides, Jim, so I'm happy to make these available or talk about them in detail. But these two slides just illustrate the fact that while responsible care has been around for quite a number of years, over a decade, and has been adopted around the world by the chemistry industry, it has evolved and importantly in the last year the large industry CEOs have made a substantial change in driving responsible care into a more third party verification commitment along the lines of what Carolyn was talking about earlier, adding that extra degree of surveillance incredibility.**

**There originally were six codes of management under responsible care. The product stewardship is one where we, sort of, pick up the ball and run with it, you know, in our industry beyond manufacturing. There has been a seventh responsible care code added in the last 18 months and that one deals with security.**

**But where we pick up CropLife and put emphasis**

**is on the, sort of, downstream distribution and use, and in partnership with the Agricultural Retailers Association CropLife are developing standards for stewardship, storage and security of many bulk package.**

**Agri-chemical products throughout the United States, we have a major pilot of that initiative in the field. In the Midwest this last growing season and plan to have it fully implemented throughout the United States in 2004, and it is a condition of membership for all CropLife members to be supportive of this system.**

**This slide just gives you one of the pages out of the checklist, if you will, of standards that our retail warehouse or wholesale warehouse distributor facility has to complete in order to be certified as an accredited warehouse.**

**We also support as an industry, training certification, in particular, for those professionals in agriculture that make recommendations to farmers for the use of crop protection products. It's called the CCA program, Certified Crop Advisor. It's actually sponsored**

**and administered by the American Society of Agronomy. There are 14,000 individuals who have been registered. CCA is working with farmers across the United States.**

**Very importantly here, the USDA has now recognized those individuals who are certified and annually recertified as CCA's qualified for technical service provider status in nutrient management and pest management under the Farm Bill. This map shows you the distributions throughout the United States and Canada of the CCA's geographic look.**

**Responsible use in integrated pest management is another component, and what we do -- it also spreads us beyond the U.S. borders in working with our international Federation of CropLife International. We have a number of initiatives that our industry supports collectively. We have just had our global CEOs agree to a $30 Million commitment to take care of the Africa stockpile problem of obsolete stocks. This is a program they're working on in conjunction with the World Bank and the Food & Agricultural Organization of the United Nations.**

**We also have safe use training education programs in all parts of the developing world for farmers that may have been behind a curve. We made a real difference in Africa, Asia and Latin America, partnering with NGOs and government agencies. It's been driven by trying to educate farmers about the need to practice IPM in the use of crop protection products.**

**In this hemisphere, we have worked closely with our Latin American CropLife counterpart organization and EPA developing and implementing now a certification program for worker protection -- focused on worker safety training in Honduras. This slide details some of those steps and I know Kevin Keeney has been very directly involved in that issue from OPP.**

**Empty container recycling is another place where we put a lot of emphasis in the stewardship cycle. In 1988 we did a survey of farmers and found that one of the most pressing problems in farmers in the United States recognized with regard to pesticides was what to do with empty containers. Today that barely gets mentioned with**

**regard to concerns of farmers because of our Agricultural Container Recycling Council that's been in place for now over a decade, and helping our industry work in conjunction with State Extension Agencies and State Departments of Agriculture, as well as USDA and EPA, in educating farmers about the need to triple rinse or pressure rinse empty containers and then get them back to the collection sites for return.**

**The ACRC membership is made up of 31 CropLife America member companies. It is exclusively member companies of CropLife right now, although we are in 13 other associations in the pesticide arena to make also a condition of membership as we have support of the recycling corporation, and it's been a substantial investment. I think our members have probably, in over 11 or 12 years, invested -- approaching $50 Million in the container recycle program.**

**So, that's just a bit of a snapshot of our commitment from the industry side. Again, I want to emphasize that we strongly support the programs of**

**farmers -- (inaudible) -- have been described in the previous two presentations, and I appreciate the chance to highlight some of these activities.**

**MR. JONES: Thanks, Jay. Any questions, comments? Larry.**

**MR. ELWORTH: Jay, one thing I would just point out maybe on your behalf is the role that in its various names CropLife America has played on some of the international regulation of pesticides as well. Your support for PFS is real important -- prime form consent was real important.**

**MR. VROOM: Right. Of course, right now we're struggling trying to get the United States of America to ratify that treaty and implement it, but hopefully we can get there and have the U.S. government at the table and the council -- the parties meet in early 2004.**

**MR. JONES: All right. Thanks, Jay. I think it's a nice way to end the day, although I hope people don't think they're actually leaving right now. A few more pieces -- the nice way to end a day. Sort of -- you**

know, when you sit around a table like this, a diverse group as we are, differences clearly occur, and you would expect that. It's good to, sort of, end the day on a note to remind us that actually we all -- there is a fair amount of common ground that we occupy. I think at that session someone highlighted how much common ground there is that's occupied by the people around this room, and that can be very helpful to know that when you're trying to work through areas where there is disagreement.

We do have one individual who signed up for public comment and as a FACA that we are, we are obligated to hear from individuals who are not on the FACA Committee themselves, and so it's important to provide this opportunity and listen to what folks have to say.

Stephen McFadden.

MR. McFADDEN: I wanted to bring to --

MR. JONES: Stephen, could you introduce yourself and who you represent?

MR. McFADDEN: Stephen McFadden. I'm a public

**interest activist. I wanted to bring the discussion back to a point made by Jennifer Sass NRDC, and pardon if I use my own work as an example.**

**In '91 I did an amateur paper out at PNNL on the human gene -- I'm using the human genome data for doing better toxicology. Coincidentally, that was the month that the entire NIH Genome database went to the patent office. I gave a talk in 8/92 at the Review of the National Toxicology Program suggesting using -- studying polymorphisms of a genobodic (phonetic) detox and John McLaughlin of NIEHS, over the next five years, started the Environmental Genome Project.**

**I presented this paper in '95 at Wright Pat and it was published in '96. By '96 industry was holding a thousand dollar an attendee conferences studying genetic polymorphisms and genobodic detox and so forth, and NIH was cataloging the -- (inaudible) -- 50s in the field by the dozens. At that time I left the field because as an individual I didn't see anything I could contribute to the field anymore.**

**Currently at Pacific Northwest National Laboratory, my hometown, BATEL (phonetic) has a $300 Million environmental intermolecular sciences lab, the largest stable of computational chemists in the world, and as of two years ago they had the sixth largest super computer in the world.**

**The point is that the public interest sector will not get access to computational genomics technology and it's not a function of their ability to comprehend it. As with the human genome project, unless there is an explicit requirement to bring in the public interest sector, it's simply not going to happen. A lot of the environmental groups studying health, like Rachel Carson Council and Beyond Pesticides, they're just trying to keep their doors open. They can't afford super computer time and so forth.**

**For instance, if I want to study the computational genomics of neurotoxic esterase, which is polymorphous, or paraoxonase, which is polymorphous, or pseudocholinestrase, which has one in 2,000 sensitive set**

**population, I'm probably not going to be able to get my hands on the super computers to do it, and this is relevant to a number of insecticides and so forth.**

**I've been told that industry has probably sequenced the human genobodic detox pathways, but that data is proprietary in terms of drugs research right now because it's useful to the various companies. Ten, 20 years from now this data may be in the public domain.**

**The point is that this is a problem of societal design and not a basic problem of science. If you're going to start talking computational genomics, the public interest sector will simply not be at the table unless you explicitedly invite them. Thank you.**

**MR. JONES: Thanks. One of the nice things about raising an issue very early in its development is you get to hear the kind of comments we heard from Stephen and from Jennifer and then you're able to respond to it, so you're not so far down the track that you can't get engagement. So I very much appreciate the comments that you've made.**

**Just a couple housekeeping things. I think we're otherwise ready to wrap up. We will -- no on will be in this room tonight, in theory. Don't leave any valuables. But if you want to leave your folders and what not, that would be fine.**

**I know a number of you have been asking about membership because we're on a two-year charter. The charter is about to expire. We've put in to re-up the charter. So before we leave tomorrow afternoon I'll just describe the process for how we basically reappoint individuals. I mean, I don't -- you know. Likely a few people will opt out and we'll need to figure out how to fill those slots and have it balanced. There's not going to be any sort of mess rotating out of membership. So, if you can rest at ease on that.**

**And then lastly, for those of you who would like to join some of us for a drink at the end of a long day, we're going to go down to the Front Page, which is one block down that way on Wilson Boulevard. It's, sort of, the same building one block down. So, if you're going**

**south towards -- well, I guess that's north. Towards DC, towards the metro, we'll be down there and have a drink together.**

**Otherwise, we had a good day and we'll be starting tomorrow morning at -- right here at 9:00. See you then.**

**(Whereupon, the meeting was adjourned.)**

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**CERTIFICATE OF TRANSCRIPTIONIST**

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